COMPARATIVE ANALYSIS OF KINEMATICS AND KINETICS GAIT PARAMETERS AMONG TRANSTIBIAL AMPUTEES OF TRAUMATIC AND VASCULAR ETIOLOGY USING PTB PROSTHESIS

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DECLARATION

I, **DR.DHINLA S,** declare that, this dissertation entitled "**COMPARATIVE ANALYSIS OF KINEMATICS AND KINETICS GAIT PARAMETERS AMONG TRANSTIBIAL AMPUTEES OF TRAUMATIC AND VASCULAR ETIOLOGY USING PTB PROSTHESIS"**is the original work done by me**, DR DHINLA S, Reg.No. 201629001**in the Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai under the direct guidance and supervision of **Prof.Dr.C.Ramesh,** Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai as guide and is submitted to the The Tamil Nadu Dr.M.G.R.Medical University, Chennai, in partial fulfilment of the board regulations for the award of the degree of **M.D.(Physical Medicine and Rehabilitation).**

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CERTIFICATE

This is to certify that the dissertation entitled **"COMPARATIVE ANALYSIS OF KINEMATICS AND KINETICS GAIT PARAMETERS AMONG TRANSTIBIAL AMPUTEES OF TRAUMATIC AND VASCULAR ETIOLOGY USING PTB PROSTHESIS"**by the candidate **DR.DHINLA S,** Reg.No. 201629001 for M.D Physical Medicine and Rehabilitation is a bonafide record of the research done by her during the period of study (2016 –2019) in the Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai –600003.

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CONTENTS

LIST OF ABBREVIATIONS

PTB	**-**	**Patellar Tendon Bearing**
PTB-SCSP	**-**	**Patellar Tendon Bearing Supracondylar Suprapatellar**
IPOF	**-**	**Immediate Postoperative Prosthesis**
EPSF	**-**	**Early postsurgical fittings**
IPSF	**-**	**Immediate Postsurgical Fittings**
3D	**-**	**Three Dimensional**
TT	**-**	**Transtibial**

LIST OF TABLES

LIST OF FIGURES

Introduction

1. INTRODUCTION

In India as per 2011 censuses about 2.68 crores persons are disabled which is 2.21% of the total population. Among this 20% are with loco-motor disabilities[1]. One of the main causes of loco-motor disability is amputation. Amputation can be defined as ‘it is the removal of part or whole of a limb.’ The word amputation means “AMBI”- means around “PUTATIO” means trimming. Amputation is done always as a last resort and all other modalities are evaluated and explored and the evidence suggests that it is absolutely necessary for a person’s health. The main causes of amputation are trauma, vascular diseases, congenital limb deficiency, infections, and tumours. National Amputee statistical database specify that lower limb amputation is significantly more than upper limb amputation. In developed countries the main cause of lower limb amputation is vascular etiology but as in case of developing country like India it is of traumatic aetiology. Vascular causes mainly include diabetes mellitus and peripheral vascular diseases .

Amputation results in change in quality of life and other hand also results in change in body structure, life style, self-concept. Thus results in greater challenges on physical and psychosocial functions of an individual.

Among lower limb amputations, transtibial amputation is the most common. It accounts for 59 % of lower limb amputations. In transtibial amputation due to the preservation of the knee joint energy consumption is far less when compared to the other higher level of amputations[2,3]. Another singular advantage of transtibial amputation is markedly reduced post-operative mortality when compared to above knee amputations[4, 5].

The ultimate goal of rehabilitation after amputation is to ambulate successfully with the use of prosthesis. Amputee rehabilitation is a complex task that ideally requires input from interdisciplinary rehabilitation team. So a well-structured rehabilitation programme helps to address the specific needs of individual patients and to bring improvement on quality of life and functional status.

'Prosthesis' can be defined as 'an artificial replacement of a part or whole of a lost limb'. Prosthesis of some types, have been used since the beginning of mankind. The earliest record of use of limb prosthesis is that of a Persian solider in 484 B.C.[6] Prosthesis use has been associated with higher level of function and independence as well as improved perceived quality of life. The quality of rehabilitation care not only determined by the prosthetic fitting but also the functional utility and satisfaction over time. Prosthetic fitting for a patient depends upon their k level, age, aetiology of amputation and associated complications.

Gait asymmetry is one of the main concerns of a unilateral lower limb amputee using the prosthesis. It can be due to prosthetic cause or amputee cause. There are several studies based on influence of the prosthetic component on the gait of amputee patients. As in case of transtibial amputees, lost part of his locomotive system is not only the static supporting structure but also dynamic function of foot ankle complex. Extensive researches had undergone based on the effect of prosthetic foot as the transtibial amputees loss ankle foot mechanism[7,8].

Lower limb prosthesis provides static structural support, and not dynamic function that corresponds to the muscle activity that lost. Although recent advances in the field of the prosthesis help the amputees to achieve near normal gait as much as possible and helps in replacement of some muscle function. In case of a transtibial amputee the influence of the sound limb in the locomotion is much more. Also good locomotion requires adaptation in the joints of remaining lower limb and also the musculature of lower limbs.

The science of gait analysis has emerged due to the inability of the human eyes to measure objectively the many interrelated components of locomotion system. The word analysis comes from the Greek 'Analyein' and means "to break up". This is precisely what the discipline involves: using measurement techniques to separate kinematic, kinetic and other parameters describing certain aspect of locomotion.

Considering the amputee patients and gait analysis, most studies had done concerning the gait asymmetry is based on the level of amputation and types of prosthetic components. Thus, there is a lack of knowledge on the gait asymmetry based on the etiology of amputation and how it influences the gait of the amputee patients. So this study focuses on influence of etiology of amputation in gait asymmetry.

Aims and objectives

2. AIMS AND OBJECTIVES

To know the effect of amputation etiology in unilateral transtibial amputees by comparing the gait parameters among vascular and trauma groups using the Patellar Tendon Bearing Prosthesis.

Review of literature

3. REVIEW OF LITERATURE

3.1 AMPUTATION

Limb amputation is one of the major surgical procedures .Evidence regarding the limb amputation can be found back in Neolithic times. Hippocrates in 4^{th} century BC reported about the ligatures. The most important steps in the evolution of limb amputation were made in the 16^{th}, 17th, 18th centuries were Ambrose Pare, a French military surgeon introduced the vessel ligation. In the beginning of 21^{st} century, limb amputation appears to be a safe operation ending up with a functional stump [9].

ETIOLOGY OF AMPUTATION

The increasing in number of amputees seen today has resulted from improvement in mechanical civilization, transport mechanism and increased medical advancement. Epidemiological results on amputees carried out in many countries extensively. Stewart and Jain et al [10] reported that majority of amputation in Scotland and UK was caused by peripheral vascular disease especially the arteriosclerosis. Warren and Kihn et al [11] studies showed that amputees who received treatment at the Veterans Administration Hospital had undergone amputation was due to peripheral vascular diseases. These reports showed that most common cause of etiology in developed countries is that of vascular disease

The scenario is different in developing countries like India. Ghosh and Lahiri et al [12] their study based on 'etiology of amputation in Kolkata' showed that trauma was the leading cause of amputation. It was similar to the study done by Sujatha et al [13], done her study in Chennai showed that trauma is the most common cause while amputation due to diabetes complication ranked second.

Assessing the cause of amputation according to age group, Lento et al [14] and Ephraim et al[15] reported that peripheral vascular disease is the common etiology in aged persons where as trauma is the cause in young age groups. Amputation due to malignancy is common in teenage groups.

When comparing the site of amputation lower limb amputation is more common than upper limb amputation. Among lower limb amputation transtibial amputation is the most common.

AMPUTATION SURGERY

The surgical technique used at the time of amputation has a major role in successful prosthetic fitting. Amputation surgery should provide adequate soft tissue padding over the stump which allows a good interface between the stump and socket. Too short a residual limb will compromise the control of the prosthesis and too long a stump limit the ability to use posterior compartment muscle for soft tissue padding [16]. Surgical techniques in transtibial amputation can be classified as follows

a) Closed amputation

- Long posterior flap
- Equal anterior and posterior flap
- Equal medial and lateral flaps
- Skew flap

b) End weight bearing amputation

c) Open amputation

- Guillotine
- Open circumferential
- Open flaps[6]

Complications following amputation also interfere with the prosthetic fitting and rehabilitation. It includes acute complications and delayed complications.

a) Acute complications include:

i. Haemorrhage
ii. Stump edema
iii. Wound gaping
iv. Infections
v. Delayed wound healing
vi. Deep vein thrombosis

b) Delayed complications include:

1. Musculoskeletal problems

Most of the musculoskeletal complications are due to the adverse sequelae of long term altered postural and gait mechanics, relative inactivity, muscular imbalance and surgical complications. These complications include the joint contracture, osteopenia/osteoporosis, early degenerative joint disease/fracture, back pain and disuse atrophy. Joint contracture is the common occurrence after amputation, as in case of transtibial amputation knee flexion contracture and hip flexion contracture is the main site of joint contracture.

Both performing and instructing range of movement exercise helps in preventing joint contracture and recreating a natural and efficient gait pattern. Ronald and Frank et al [24] studies showed that immediate postoperative prosthesis as well as bi–valved casts can aid in prevention of joint contracture and have the added advantages of protecting the operative wound and controlling post operative limb swelling. Increased forces on the joints of intact limb results in increased prevalence of osteoarthritis. Asymmetries in gait and increased dependence on proximal musculature have also been associated with increased incidence of osteoarthritis and other musculoskeletal pain[26]. Many of these complications can be avoided by using a good rehabilitation, patient care and education which should start immediate postzoperatively and continues throughout the remainder of patient’s life.

2. Dermatological problems

Bui and Raugi et al [17] study showed that 41% of patients with lower limb amputation experience skin problems in the stump. Dermatological issues may be due to complication of surgery, repetitive injury due to poor socket fitting or reaction to occlusion of the skin. Wound dehiscence is one of the immediate post-operative skin complications. The skin of the residual limb should be properly monitored by the patient and the physician for any excessive pressure or shear. These pressures can be caused by some suboptimal socket fit and/or prosthetic alignment.

Hachisuka et al [19] in his study showed that hyperhidrosis was the common complaint in prosthetic wearer. Conservative management for this is changing to a breathable socket liner. Studies done by kern et al [19] showed that Botulinum toxin was effective treatment in refractive cases. Skin eruptions can be reduced with optimal skin hygiene and liner care. In patients with amputation due to vascular aetiology xeroderma or dry skin is a common occurrence because of impairments of cutaneous glands.

3. Pain

Pain is one of the main causes of morbidity in the immediate postoperative period as well as long term. Two fundamental types of pain are phantom limb pain and residual limb pain. Phantom limb pain can be defined as 'painful sensations perceived in the missing limb after amputation'. It has been postulated that both central and peripheral factors and as well as psychological factors have a role in phantom limb sensation. Various studies had done, based on the phantom limb sensation. The pharmacological approach to the phantom limb sensation is similar to other form of neuropathic pain that includes the Tricyclic antidepressant, Gabapentin and newer classes of antidepressants, etc. Mirror therapy and mental imagery techniques have also used in early postoperative and chronic phantom limb pain [20]. Surgical modalities include anterolateral cordotomy, thalmictracotomy and electrical stimulation of the dorsal column of spinal cord.

Residual limb pain includes neuropathic pain and somatic pain. Neuropathic pain includes neuroma and complex regional pain syndromes. ‘Neuroma is the bulbous swelling at the cut end of the nerve ’. Management of neuroma includes

a) Pressure relief in the prosthesis
b) Analgesics
c) Physical modalities including ultrasound and TENS
d) Injection of local anaesthetic with or without steroids
e) Desensitization by tapping and kneading techniques
f) Surgical excision of neuroma.

The prevalence of pain in areas other than around the site of amputation is also high, these includes chronic back pain, neck pain and contralateral limb pain. These secondary areas of pain may be attributable to overuse syndrome and compensatory strategies.

4. Psychiatric

Kashani et al [21] studies showed that amputation is found to be associated with psychiatric conditions, which have been associated with negative impact on rehabilitation outcomes in chronic conditions. Darnall et al [22] done a study based on the depressive symptoms and mental illness among amputee patients and it showed that depression is major co morbidity among amputee patients with prevalence rate between 28% and 42% as compared with 5.4 % in the general population. Also high rates of acute stress disorders and post traumatic stress disorders reported among traumatic amputee patients[23].These increased prevalence of psychiatric symptoms highlights the need of concomitant psychiatric support both immediately after amputation and long term, to maximize the rehabilitative outcomes and successful reintegration of patients into community and life roles.

AMPUTEE REHABILITATION

The ultimate goal of rehabilitation after amputation is to ambulate successfully with the use of a prosthesis. Amputee rehabilitation is a complex task that ideally requires input from interdisciplinary rehabilitation team. Amputee rehabilitation is done in the following phases that includes.

1). Pre amputation counselling

2). Amputation surgery

3). Acute post amputation care

4). Pre prosthetic training

5). Prosthetic fitting and training

6).Reintegration into community

7). Long-term follow up.

These help the patients to receive a well-structured rehabilitation programme and which helps to address the specific needs of individual patients and to bring improvement on quality of life and functional status.

Table 1: STAGES OF AMPUTEE REHABILITATION

Pre amputation counselling	1. Communication involving the patient, family, physiatrist regarding the need of the surgery and prosthetic fitting. 2. 2.Pre rehabilitation exercise programmes.(involving other limbs and trunk muscles)
Amputation surgery	It is to achieve most distal level with clinical condition, less functional loss, less energy for ambulation with the prosthesis
Acute post amputation care	Control of pain, psychological support, early mobilization, prevention of edema ,wound healing
Pre prosthetic training	Maintaining shape and position of the stump, muscle strengthening, improving the range of movement, transfer and mobility techniques
Prosthetic training	Prosthetic fitting and its maintenance, gait training
Reintegration into community	Resuming the social roles, recreational activities
Long term follow up	Lifelong functional and prosthetic assessment and psychological supports.

Preprosthetic training plays a major role in amputee rehabilitation. It helps in the successful outcome of prosthetic fitting and usage. The final outcome on prosthetic usage depends upon the age, clinical condition and motivation during preprosthetic training. It includes position of the stump, crutch muscle strengthening exercise, active ROM exercise, wheelchair mobility, self-care, patient and family education.

Prosthetic training programme is primarily focussed on the selection fabrication and application of the prosthetic device, as well as on the pre training rehabilitation and prosthetic ambulation mastering. It includes prosthetic fitting, donning and doffing training, skin care training, gait training and maintenance of the prosthesis.

Mastering of the prosthesis aided activities, that is the functional rehabilitation goal attainment follows the subsequent algorithm: 1. Mastering of the prosthesis donning and doffing; 2.Prosthesis aided standing and sitting exercises, followed by the prosthetic ambulation exercises that make use of parallel bars and strive to set the walking biomechanics in order as much as possible; 3.Prosthetic ambulation outside the parallel bar/uneven surface; 4.Sitting and getting up plus prosthetic transfers; 5.Transversing minor barriers; 6.Climbing stairs; 7.Prosthetic ambulation in natural environments; 8.Getting in and out of a vehicle; 9.Prosthesis on and off sporting activities (younger amputees) ; 10.Prosthesis on fall and getting up scenarios (younger amputees).

3.2 PROSTHESIS

As mentioned earlier artificial limb of some kind have been used from ancient periods. A soonest record of utilization of prosthesis is that of a Persian soldier, Hegesistratus. The vast majority of the prosthesis of that time was made to conceal deformity. In seventeenth through nineteenth hundreds of years built up the primary non locking transtibial prosthesis, which would later turn into the outline for current joint and corset device [27].The present prosthesis are substantially lighter, made of plastic and composite material to furnish amputees with the most utilitarian devices. Prosthetic fitting got more revolutionized with the introduction of Osseo integrated prosthesis.

TYPES OF PROSTHESES

There are five types of prostheses: post operative, initial, preparatory, definitive and special purpose prostheses. Only some amputees may be desirable to have progression through all the five levels, some selected patients will receive the postoperative or initial prostheses, which are directly fitted on the residual limb. Almost all the amputees will have preparatory and definitive prostheses, but a lesser number of amputees will receive special purpose prostheses for sports activities, etc.

1. Post-operative prostheses

'Post-operative prostheses are by definition provided within 24 hrs of amputation'. They are also referred by various name 'immediate post surgical prosthetic fitting' (IPSF) and 'immediate post-operative prosthesis' (IPOF)

IPOF traditionally have been thigh-high cast with a pylon and foot attached which is given in the operating room itself. Prefabricated devices are also now available. These devices allow for earlier bipedal ambulation. Only limited weight bearing can take place with an IPOP, and patient compliance is important for such success [61]. Cohen et al [62] in his study shown as increased wound dehiscence and infection with these devices. Benefits of the IPOF include low percentage of significant limb complications, few surgical revisions and a short time period to definite prosthesis fittings. Kihn et al [63] described that patients were emotionally less troubled post operatively because the presence of a prosthetic foot aided in self-imaging. Disadvantages include reduced access for wound inspection, tissue necrosis because of incorrect wrapping of the gauze bandage, possible mechanical tissue trauma inside the cast, and the requirement of skilled prosthesis team[64].

2. Initial prosthesis

The initial prosthesis is sometimes used in alternative to post surgical fitting and is provided as early as the sutures are removed. 'This is also referred as early post surgical fittings (EPSF)'. Because of the usual rapid atrophy of the residual stump; the EPSP is generally directly molded on the residual stump by using plaster of Paris or fibre glass bandages. These devices are used during the initial phases of healing, usually from 1 to 4 weeks after surgery, until the suture line is healthy and the skin can bear the stresses of more intimate fittings.

3. Preparatory prosthesis

The preparatory prosthesis is used during the early few months of the comprehensive rehabilitation of amputee to alleviate the change in to a definitive device. They speed up the rehabilitation programme by permitting ambulation before the residual stump has totally matured. The preparatory prosthesis can use for a period of 3 to 6 months following the date of amputation however, that time can differ depending on the time taken for stump maturation and on other factors such as medical issues and body weight alterations.

4. Definitive prosthesis

The definitive prosthesis is prescribed only after the patients stump has matured to ensure that the fit of the new prosthesis will last for long and it can be tolerate by the residual limb. The prescription of the definitive prosthesis is based on the patient skill when he had using the preparatory prosthesis. The average life span of a definitive prosthesis is from 3 to 5 years. Changing of the prosthesis is mainly due to the residual limb changes such as atrophy, weight changes,etc.

5. Special use prosthesis

A certain number of patients will require special use prosthesis, specifically for activities such as sports. It is useful to the amputees who are active in participating in a full range of sports and recreational pursuits.

GENERAL PRESCRIPTION GUIDELINES OF THE PROSTHESIS

Prescription of prosthesis is influenced by many factors. That includes residual limb length, muscular strength, balance, coordination, vision and motor control all affect stability during prosthetic ambulation. The quality of residual limb skin should be considered in selecting the appropriate prosthetic suspension and interface system. Hand function, vision and cognitive abilities need to be considered with regarding the donning and doffing and also during prosthetic training period. The factors in order:

1. Weight bearing

For lower limb prosthesis, the weight bearing characteristics of the socket are the most important factor. If the patient has adherent scar, neuroma, or skin irritation, specific changes must be made in the socket design. Special impact absorbing materials might be used to broaden the weight over a greater surface area.

2. Suspension

There are numerous strategies for suspension, going from very basic leather belts to refined suction sockets. Each of them must be evaluated separately and prescribed according to the status of each amputee; changing of muscle bulk in the residual stump is a key factor.

3. Activity level

A person using the prosthesis only indoor obviously presents different considerations from someone who anticipates being active in his job and in competitive sports. Activity level of an amputee patient had influences on weight bearing, suspension and structural strength and quality of the prosthesis.

The centre of Medicare and Medicaid services (CMS) has published a functional classification system for prescription of the prosthesis based on the potential or functional ability of the person. It is referred as Medicare functional classification levels (MCFL), the K level modifiers, or the functional index level.

Table 2: MEDICARE FUNCTIONAL CLASSIFICATION LEVEL

Functional index level	Description
K0	No ability or potential to ambulate or transfer with use of a prosthesis and the prosthesis does not enhance the quality of life.
K1	Ability or potential to ambulate with a prosthesis for household distance on a level surface at a fixed cadence
K2	Ability or potential to ambulate limited community distance and traverse low-level environmental barriers at a fixed cadence
K3	Ability or potential to ambulate unlimited community ambulatory and traverse most of the environmental barriers and also with variable cadence.
K4	Ability or potential to exceed normal ambulation activities and use prosthesis for activities exhibiting high impact, stress or energy levels.

4. Structure of the prosthesis

'There are two basic structural types: endoskeletal (modular) or exoskeletal (crustacean)'. Endoskeletal prosthesis consists of internal tubes and components covered with a foam outer cover. They are ending up progressively prevalent as a result of the interchange ability of components for trial or repair, moderately light weight and the great appearance. Exoskeletal prosthesis consists of polyurethane covered with a rigid plastic lamination. For exceptionally dynamic persons, the exoskeletal prosthesis is more solid since the foam covering of the endoskeletal designs tear easily and requires substitutions at intervals.

5. Prosthetic components

Each components of the prosthesis should meet the functional goals of the amputee patient. Due to the large and expanding number of options now available in prosthetic components, close consultation with the prosthetist is very important.

Essential elements in prosthetic prescription include.

a) Socket
b) Interface
c) Suspension
d) Shank piece
e) Ankle foot complex
f) Knee unit if knee disarticulation or above
g) Hip joint if hip disarticulation or above
h) Extras (rotators, covers, etc.)

6. Expense

The expense of the prosthesis may vary depending on the type of materials and prosthetic components used. Light weight prosthesis is often made from titanium or carbon fibre, aerospace materials that are expensive and difficult to fabricate, which may increase the cost of components. Each component should be precisely considered to give the most financially-effective solution that completely addresses the issues of the individual amputees.

7. Unique considerations

Many patients may present with unique factors that should be addressed in the fabrication of the prosthesis. In case of carpenters, they needs more comfort during kneeling position from the prosthesis than a normal amputee. The cultural background also have influence in the prosthesis prescription as in case of Indian amputees, requires bare foot walking when entering a home or temple. Such generic individual factors should be considered to guarantee the best possible match between the prosthetic design and amputee objectives.

TRANSTIBIAL PROSTHESIS

Transtibial prosthesis components are constituted by the socket, suspension, shin piece, ankle foot complex.

Table 3: TYPES OF EACH COMPONENTS OF TRANSTIBIAL PROSTHESIS

COMPONENTS	TYPES
Socket	1.Conventional 2.Patellar tendon bearing 3.Prostheses tibial supracondylien 4.Bent knee 5.Slip socket 6.Flexible socket with rigid external frame
Suspension	1.Cuff suspension 2.Thigh corset and side joints 3.PTB supracondylar suprapatellar suspension 4.PTB supracondylar suspension 5.Auxiliary suspension with sleeve 6.Liner with pin locking 7.Suction with or without liner 8.Vaccum
Ankle foot complex	1.Non-articulated Solid ankle cushion heel Solid ankle flexible endoskeleton foot 2.Articulated Single axis Multi axis 3.Energy storing/dynamic elastic response 4.Microprocessor control 5.Microprocessor control with internal power 6.Special activity feet

The prosthetic foot is an important, multifaceted part of the transtibial prosthesis. The main role of the prosthetic foot is to replace the anatomic foot and ankle. The function of the prosthetic foot includes.

1. Joint simulation

In normal human motion, the foot, ankle and the subtalar joint allow inversion and eversion and the other joints of the foot allows smooth rollover during the heel off and the toe off. These motions are vital to normal energy efficient gait and are particularly important during ambulation on uneven ground. A successful, energy efficient gait with a prosthetic foot is therefore largely dependent upon the ability of the foot to compensate for the absence of normal function.

2. Shock absorption

The foot absorbs the impact of heel strike and weight acceptance without transmitting excessive forces to the residual limb. Too much shock absorption, in contrast, might fail to generate the normal knee flexion moment when the foot is flat and results in an unacceptable gait pattern.

3. A stable weight bearing base of support

This is essential when the amputee is standing or during the stance phase of gait cycle.

4. Muscle simulation

In normal human gait, in order to prevent foot slap after heel strike, the dorsiflexor group of muscles eccentrically lengthens. During midstance and heel off, the plantar flexors balance the ankle joint and oppose the intense dorsiflexion moment that occurs during these phases of gait. During running or rapid walking, the plantar flexors are actually push off and assist in propelling the weight of the body forward. The primary way in which the prosthetic foot substitutes for muscle activity are through stance phase stability. In addition some prosthetic foot allows controlled plantar flexion and dorsiflexion, thus stimulating both dorsiflexors and plantaflexors. Through dynamic response principles, a few specialized feet actually provide some degree of dynamic push off during the late stance.

5. Cosmesis

The function of the prosthetic foot is of main concern to the prosthetist, but the significance of cosmesis cannot be ignored. The design of a particular foot may enhance or diminish its cosmetic appearance.

ADVANCES IN PROSTHESIS -OSSEOINTEGRATION

The osseointegration is a more up to date and another method of attaching the prosthesis to human body. The idea of osseointegration goes back to 1960s when it was found that titanium is bone friendly. Swedish Professor Branemark had done research on the use of osseointegrated implants in the dental surgery. The concept was extended in 1990s and the transfemoral amputee persons were fitted with osseointegrated framework. In this the prosthesis is directly attached to the bone. This require two stages of surgical procedures. In the primary stage implant which is a threaded titanium material is inserted into the marrow cavity of the residual stump. This is known as fixture. This fixture will get integrated to the bone with time. The second surgery is conducted after six months. The abutment which is a titanium extension is inserted into the fixture and anchored with abutment screw. The abutment penetrates the skin and protrudes out. The remaining parts of the prosthetic components can be directly fixed to the abutment in the accompanying phase of rehabilitation. This leads to a gradual and progressive weight bearing of the prosthesis. The whole rehabilitation will take 6 months for appropriate weight bearing and gait training. So from amputation to independent walking with the osseointegrated prosthesis will require at least one year. The hip range of motion in the osseointegrated prosthesis is not restricted unlike the other sockets. The cumulative survival rate, of the osseointegrated prosthesis shown a better results with prosthetic use and mobility [65]. Two years follow up of transfemoral amputee patients with the osseointegrated prosthesis demonstrated better quality of life and prosthetic function. Hagberg et. al [66] done study on the walking ability and energy consumption with the osseointegrated and the conventional transfemoral prosthesis. They found that amputee persons with the osseointegrated prosthesis are superior to the conventional transfemoral prosthesis and the amputee with osseointegrated prosthesis walk with higher speed and lesser energy expenditure.

The advantages of the osseointegrated prosthesis are:-

a) Since there is no socket, the inconvenience, skin irritation, sweating, concentrated pressure and pain occurring in the stump- socket interface can be avoided.
b) The prosthesis can be easily removed from the abutment. Hence donning and doffing is easy.
c) The suspension is good, since it is directly attached to the bone.
d) The joint movements are not restricted since there is no socket enclosing around the residual stump.
e) The more natural view of the prosthetic limb, which is known as osseoperception .

The disadvantages are:-

a) Wide range of rehabilitation and long time interval between amputation and prosthetic walking.
b) Risk of implant related complications like infection, implant loosening and failure.
c) Risk of fractures.
d) Permanent abutment can lead to poor cosmesis.
e) High impact activities like running and jumping are restricted. 6. Regular skin care for the abutment area is required.

PTB PROSTHESIS

In this study all subjects were used Patellar Tendon Bearing prosthesis as a primary mode of ambulation

Fig 1: Patellar Tendon Bearing prosthesis

Components of Patellar Tendon Bearing prosthesis used in this study are

1. **Patellar Tendon Bearing socket:** This socket is primarily indicated stump with good soft tissue/muscle coverage and no sharp bony prominence.

Advantages:

a) Perspiration does not corrode the socket

b) Less bulky at the knee than with an insert

c) Easy to keep clean

d) Contours within the socket do not compress or pack down with use

e) Reliefs or modifications can be located with exactness.

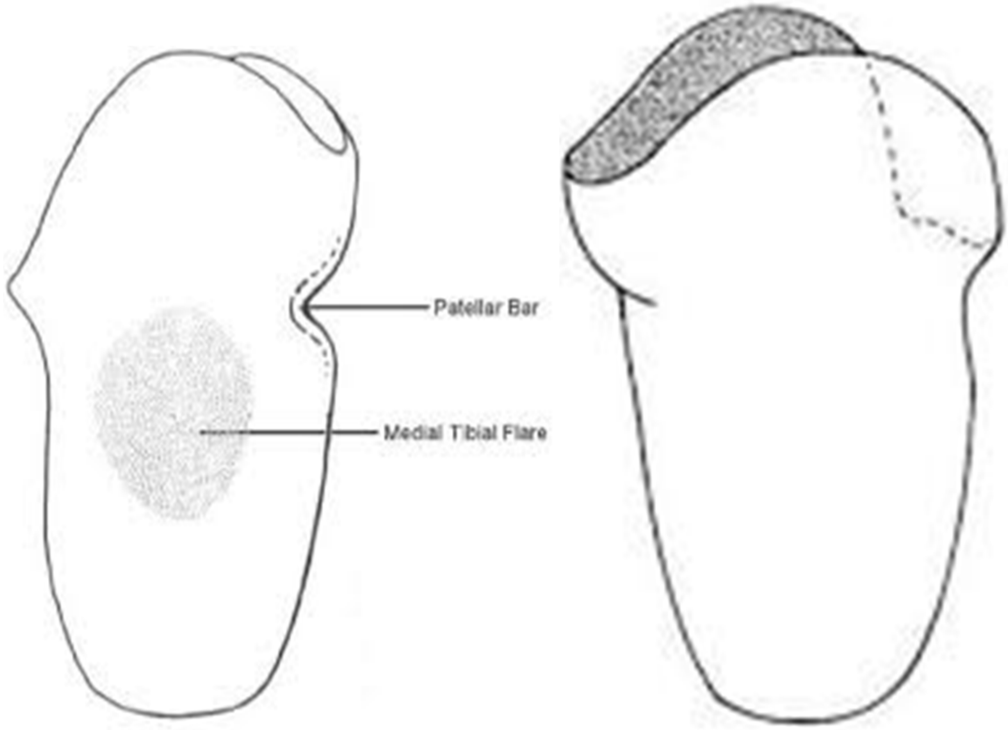

Fig 2: PATELLAR TENDON BEARING SOCKET

Disadvantages:

a) Requires extra skill in casting and modification

b) Difficult to fit bony or sensitive residual limb

c) Not as easily modified as a socket with a liner

2. Supracondylar Cuff suspension

It encircles the thigh and winds over the femoral condyles and proximal part of the patella. Attachment points on the socket are slightly posterior to the sagittal midline so as to oppose hyperextension forces at the knee and to enable the limb to pull back slightly from the socket during knee flexion.

Advantages:

(a) Adjustability

(b) Ease of donning and doffing by the patient

(c) Adequate suspension for the majority of transtibial amputee

(d) Provides moderate control of knee extension

(e) Easily replaced.

Disadvantages:

a) During knee flexion ,may pinch soft tissue between the posterior proximal end of the socket brim and the cuff

b) May restrict circulation

c) Provides no added mediolateral stability

3. Exoskeletal shin piece (Crustacean):

It is a hard outer plastic shell, molded to the shape of leg.

Advantages:

a) Durable

Disadvantage:

a) Does not allow alignment change after finishing

4. SACH foot (Solid Ankle Cushion Heel)

Solid heel is directly attached to the ankle block and there is no joint ankle. Cushion heel is made of alternating layers of soft and hard rubber. The compressibility of the cushion heel depends on patient weight and activity. The compression of the cushion heel during heel strike simulates the plantarflexion action.

Advantages:

a) Light weight & Durable

b) Little maintenance is needed

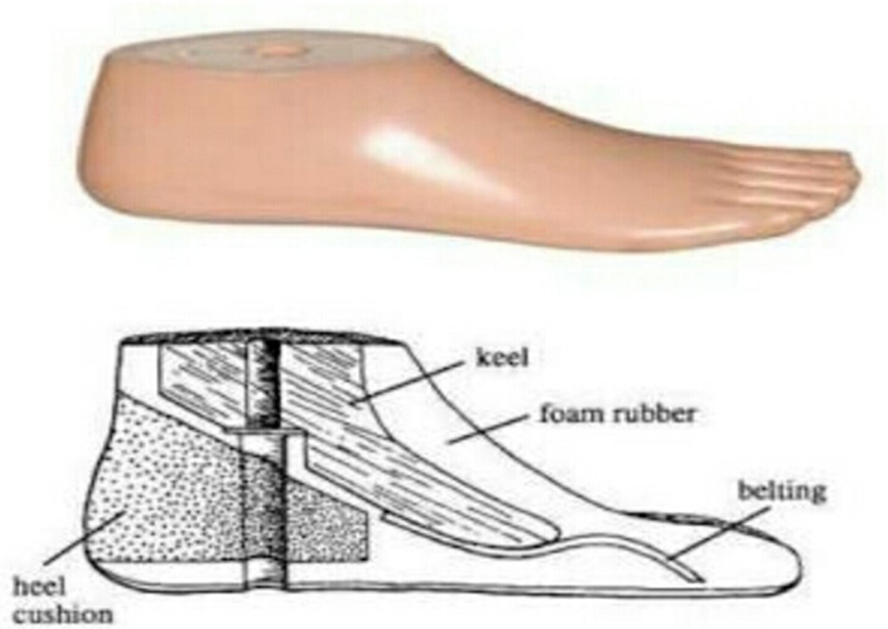

Fig 3: SACH FOOT

BIOMECHANICAL VARIABLES IN TRANSTIBIAL PROSTHETICS

The successful fitting of the transtibial prosthesis requires a careful comprehension of the biomechanical factors. Biomechanical factors in transtibial prosthesis can be divided into four categories:

1) Socket fit

2) Alignment

3) Foot function

4) Suspension

1. BIOMECHANICS OF TRANSTIBIAL SOCKET FIT

Prosthetic socket is the primary connection between the stump and the prosthesis. It must provide comfort and function to the patient under the action of two force system: the weight of the body due to gravity & forces applied to the residual limb through contact with socket.

a) Pressure tolerance of residual limb tissue.

During axial loading soft tissues are displaced, so a socket that makes equal contact with the surface area of the residual stump may results in greater pressure over the bony structure and lesser pressure over the soft tissue. In order to apply greater pressure to pressure tolerant area and less to pressure sensitive areas, tissues are selectively loaded through inward contours over weight bearing areas and relief over sensitive surfaces.

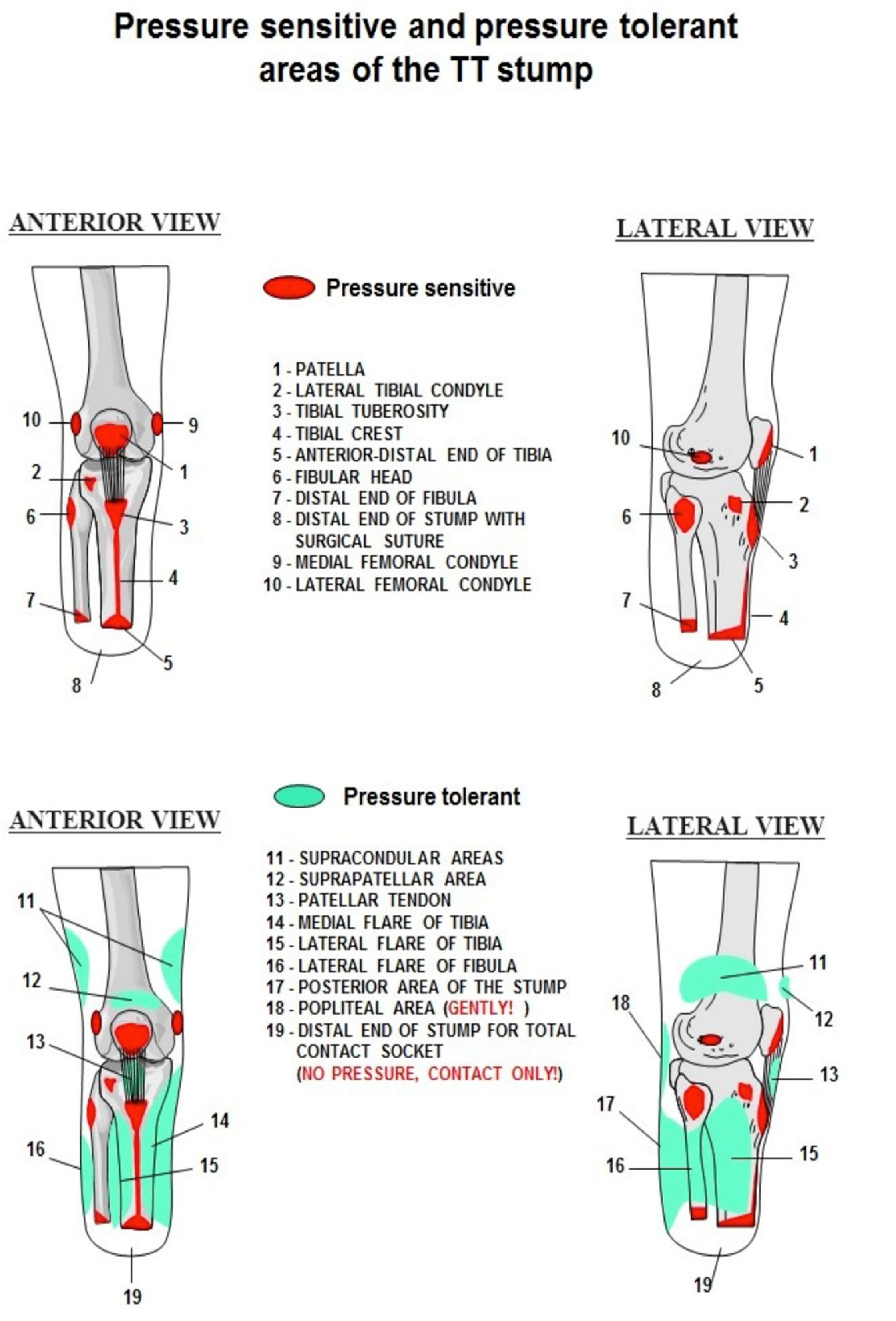

Fig 3: PRESSURE TOLERANCE OF TRANSTIBIAL RESIDUAL STUMP

b) Modification of dynamic force

The major dynamic force to consider is anteroposterior and mediolateral force. Anteroposterior force generated from heel strike to foot flat. The resulting forces between the socket and the residual limb are concentrated on the anterodistal portion of the tibia and posteroproximal soft tissue. The socket therefore must provide even pressure distribution in the popliteal area and anterodistal relief coupled with anterior, medial and lateral counter pressure to prevent excessive pressure over the distal end of the tibia.

Mediolateral force occur during single limb support on the prosthetic side when ground reaction force may result in valgus or varus forces .Forces are generally increased over the proximomedial and distolateral aspect of the residual limb. Proximomedial forces are focused upon the pressure tolerant area medial femoral condyle and medial tibial flare. But distolateral forces can produce too much pressure on the distal end of the fibula. Socket modification to prevent this include relief for the distolateral aspect of the fibula, lateral stabilizing pressure along the shaft of the fibula, and lateral stabilizing pressure over the anterior compartment (pretibial muscle group)

2. BIOMECHANICS OF TRANSTIBIAL PROSTHETIC ALIGNMENT

'Alignment refers to the spatial relationship between the prosthetic socket and foot'. This unit allows for anteroposterior and mediolateral foot positioning, anteroposterior and mediolateral tilting of the socket, height adjustment and rotation of the prosthetic foot.

Appropriate anteroposterior foot situation will statically result in an even weight conveyance between the heel and toe segment of the foot. Proper anteroposterior foot positioning will result in even weight distribution between the heel and toe portion of the foot statically. Dynamically it will result in controlled knee flexion after heel strike, smooth rollover with a limited recurvatum tendency and heel off prior to initial heel contact on the contralateral foot.

Appropriate anteroposterior socket tilt will statically result in a attitude of initial flexion, thus loading that area that are pressure tolerant. Dynamically it also provides ,proper flexion improves the weight bearing characteristics of the socket and quadriceps muscle on stretch to give a mechanical advantage for the control of the prosthesis and limit recurvatum forces during midstance and terminal stance.

Appropriate mediolateral foot positioning will bring about the statically proper loading of the proximomedial and distolateral aspects of the residual limb. Dynamically it will duplicate genuvarum moment at midstance and provide optimum loading of the medial tibial flare during stance phase

Foot rotation can also affect the prosthetic gait. During stance phase tendency to fall over the foot is resisted by the counter force of the foot lever arm. Rotation of foot directly affects the length and the direction of force exerted by the lever arm.

3. BIOMECHANICS OF THE PROSTHETIC FEET

There are six variable factors to be considered while choosing a prosthetic foot. They are alignment, length of the toe lever arm, width of the keel, flexibility of the keel, durometer of the heel cushion and fit of the prosthetic foot within the shoe/chappal.

The wider keel width provides a greater medial lateral stability during stance phase by widening the base of support. Also keel flexibility provides for a smoother gait pattern with a less pronounced transition at toe break.

The heel cushion absorbs shock and helps in initiate knee flexion during loading response. Greater heel stiffness brings about a greater knee flexion forces during heel strike and also diminishes the shock absorption. Alternatively, decreased heel stiffness brings down the knee flexion forces and increased shock absorption.

3.3 GAIT AND GAIT ANALYSIS

The word gait describes ‘the manner or style of walking’.

HISTORY

The historical background of gait analysis has demonstrated a stable progression from early descriptive studies through progressively more sophisticated methods of measurement, to mathematical analysis and mathematical modelling. Great surveys of the early long period of gait analysis have been given by Garrison et al [28]. The later history of gait analysis and also of clinical gait analysis in particular was covered in outstanding review papers by Sunderlands [29].

Walking was undoubtedly been observed ever since the time of the ancient men. The earliest account using a truly scientific approach was in the classic 'De motor Animalum', published in 1682 by Boreli who worked in Italy. He measured the centre of gravity of the body and describes how balance is maintained in walking by constant forward movement of the supporting area provide by the feet.

In kinematic measurements Marey et al published a study of human movements in 1873.He made multiple photographic exposures, on a single plate of a subject with brightly illuminated stripes on the limbs. He additionally researched the way of the centre of gravity of the body and the pressure underneath the foot[30].

In 19th century the most serious application of the mechanism of human gait was the publication of 'Der Gang des Menscher,' in Germany in 1895 by Brauce and Fischer. They used fluorescent strip lights on the limbs. The subsequent photographs were utilized to decide the three dimensional directions, speeds and accelerations of the body segments[31].

Further progress is followed by the development of force plates .This instrument has contributed exceptionally to the logical investigation of gait and is presently a standard instrument in gait research facilities. It quantifies the direction and magnitude of the ground reaction force underneath the foot. It gauges the course and magnitude of the ground reaction force constrain underneath the foot. An early design was described by Amar et al in 1924 and an improved one by Elftmann et al in 1938[32].

For a full understanding of gait, it is important to know which muscles are active during the distinctive parts of the gait cycle. The role of the muscles was studied by Scherb et al in 1940s, at first by palpating the muscles as his subject strolled on a treadmill ,at that point later by the utilization of electromyography.[33]

DISPLACEMENT OF BODY DURING NORMAL WALKING

Synchronous movements of all the major parts of the body occur during walking at moderate speeds. The pelvis tilt, rotates and undulates as it moves forward. The segments of the lower limb show displacements in all three planes of space, while the shoulders rotate and the arms swing out of phase with the displacements of the pelvis and legs. The centre of mass of any body is a point such that if any plane is passed through it, the mass moments on one side of the plane are equal to the mass moments on the other. If the body is suspended at this centre of mass, it will not tend to tip in any direction. During walking, the centre of mass of the body, although not remaining in an absolutely fixed position, tends to remain within the pelvis.

In normal level walking, the centre of mass describes a smooth sinusoidal curve when projected on the plane of progression. The total amount of vertical displacement in normal adult men is typically about 5 cm at the usual speeds of walking. The centre of mass falls to its lowest level during the middle of double weight bearing, when both feet are in contact with the ground. The centre of mass of the body is also displaced laterally in the horizontal plane. In this plane, too, it describes a sinusoidal curve, the maximal values of which alternately pass to the right and to the left in association with the support of the weight-bearing limb.

1) Pelvic rotation

In normal level walking, the pelvis rotates about a vertical axis alternately to the right and to the left, relative to the line of progression. The magnitude of this rotation is approximately 4 degrees on either side of the central axis or a total of some 8 degrees.

2) Pelvic tilt

In normal walking, the pelvis tilts downward in the coronal plane on the side opposite to that of the weight-bearing limb (positive Trendelenburg). At moderate speeds, the alternate angular displacement is about 5 degrees. The displacement occurs at the hip joint, producing an equivalent relative adduction of the supporting limb and relative abduction of the other limb, which is in the swing phase of the cycle. To permit pelvic tilt, the knee joint of the non weight-bearing limb must flex to allow clearance for the swing-through of that member.

3) Knee flexion

A characteristic of walking at moderate and fast speeds is knee flexion of the supporting limb as the body passes over it. This supporting member enters stance phase at heel strike with the knee joint in nearly full extension. Thereafter, the knee joint starts to flex and keep on doing until the foot is level on the ground.

A typical magnitude of this flexion is 15 degrees. Just before the middle of the period of full weight bearing, the knee joint once more passes into extension, which is immediately followed by the terminal flexion of the knee. This begins simultaneously with heel rise, as the limb is carried into swing phase. During this period of stance phase, occupying about 40% of the cycle, the knee is first extended, then flexed, and again extended before its final flexion. During the beginning and end of the stance phase, knee flexion contributes to smooth the abrupt changes at the intersections of the arcs of translation of the centre of mass.

These three elements of gait pelvic rotation, pelvic tilt, and knee flexion during early stance phase, all act in the same direction by flattening the arc through which the centre of mass of the body is translated. The first (pelvic rotation) elevates the ends of the arc, and the second and third (pelvic tilt and knee flexion) depress its summit.

The additional mechanism acting that smooth the pathway of centre of gravity includes movements in the knee, ankle, and foot. The foot enables the pathway of displacement of the knee to remain relatively horizontal during the entire stance phase. This, in turn, allows the initial knee flexion to act more effectively in smoothing the pathway of the hip. At the time of heel strike, the centre of mass of the body is falling. This downward movement is decelerated by small degree of flexion of the knee in opposition to the resistance of the quadriceps. After heel strike, the foot is plantar flexed against the resisting tibialis anterior muscle. This plantarflexion of the foot occurs about a point where the heel contacts the floor. Rotation about this point causes the leg to undergo relative shortening and the ankle to be carried slightly forward in the direction of progression until the foot is flat. Contraction of the quadriceps acting on the knee and the tibialis anterior muscle on the foot causes these movements to be slowed, and the downward motion of the centre of mass of the body is smoothly decelerated.

The centre of mass begins its upward movement immediately after it has passed in front of the weight-bearing foot, as the forward momentum of the body carries the body up and over the weight-bearing leg. After the centre of mass has passed over and in front of the foot, its immediate fall is delayed by relative elongation of the weight-bearing leg through extension of the knee, plantar flexion at the ankle and supination of the foot. All these elements acting in proper relationships lead to the smoothing of the passage of the centre of mass into an approximately sinusoidal pathway lateral displacement of the body the body is shifted slightly over the weight-bearing leg with each step; there is a total lateral displacement of the body from side to side of approximately 4 to 5 cm with each complete stride. The motion is formed by the horizontal shift of the pelvis and adduction of hip. This lateral displacement can be increased by walking with the feet more widely separated and decreased by keeping the feet close to the plane of progression.

GAIT CYCLE

'Gait cycle is defined as the time interval between two successive occurrences of one of the repetitive events of walking.' The gait cycle is subdivided into seven periods. Four which occur in stance phase, where the reference limb is on the ground and three in the swing phase, when the foot is moving forward through the air. The stance phase also called the support phase or contact phase, last from initial contact to the toe off. It accounts for approximately 60 percentages of gait cycle.

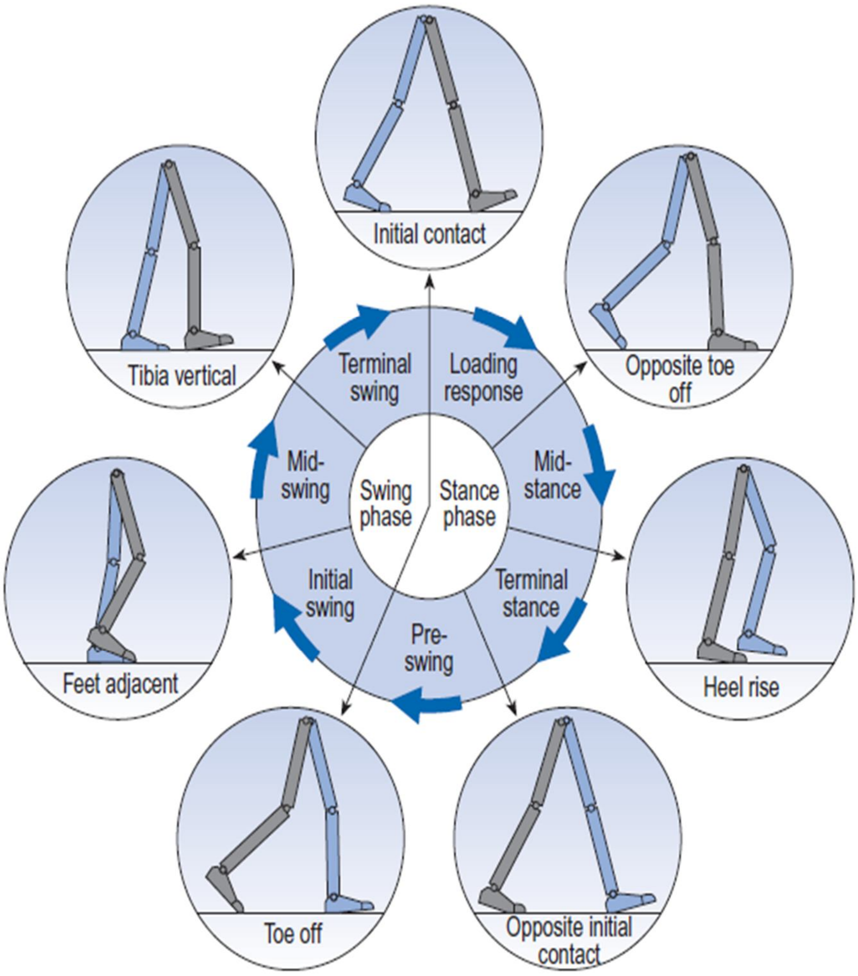

Fig 5: POSITIONS OF THE LEGS DURING A GAIT CYCLE

It is subdivided into:

a) Loading response
b) Midstance
c) Terminal stance
d) Preswing

The swing phase lasts from toe off to next initial contact. It accounts for approximately forty percentages of the gait cycle. It is subdivided into:

a) Initial swing
b) Mid-swing
c) Terminal swing.

The duration of complete gait cycle is known as cycle time which is subdivided in to stance time and swing time.

Gait terminologies

- **Stride**: The basic unit of gait which includes all activity between the initial contact of a limb (reference limb) and subsequent initial contact of the same limb.
- **Stride length**: The distance travelled during one gait cycle.
- **Step length**: Initial contact to the end of pre-swing on the same limb.
- **Step width**: The distance between the centres of the feet during double support phase of the gait

- **Cadence**: The number of steps in a given period of time. Average cadence is 80 to 110 steps/min.
- **Speed** of the walking is the distance covered by the whole body in a given time. It should be measured in meters per second. Speed can be calculated from cadence and step length using the formula:

  'Speed (m/s) = stride length (m) × cadence (steps/min)/120'

  if cycle time is used in place of cadence:

  'Speed (m/s) = stride length (m)/cycle time (s)'

The **toe out** is the angle in degrees between the direction of progression and a reference line on the sole of the foot (a line intersecting the centre of the heel and the second toe).

Kinematics is the term used to describe movements without considering the internal or external forces that caused the movements. These measures include position, velocities and accelerations of the body markers or body segments. The joint angles are expressed as absolute positions in space or as relative angles of joints between adjacent segments such as hip or knee. Sagittal plane motions includes hip flexion - extension, knee flexion- extension and ankle plantarflexion and dorsiflexion. Non-sagittal plane motions are pelvic rotation, hip internal and external rotation. Hip abduction and adduction and subtalar joint motion.

Kinetics is concerned with the forces acting on the body that are the cause of the movement. A kinetic analysis is performed to understand the forces acting on the foot by the supporting surface, the forces produced by the muscles, the moments produced by the muscles crossing the joints, the mechanical power absorbed or generated by those muscles and energy pattern of the body during walking.

TRANSTIBIAL PROSTHETIC GAIT DEVIATIONS

Observational gait analysis also have important role in providing information about the prosthetic fit, alignment & function for the individual patient. Prosthetic gait deviations seen in transtibial amputation are:

1. Between initial contact and mid-stance

a) Excessive knee flexion: During normal gait, immediately after heel strike knee flexes 10 -15° during loading response. It reduces movement of centre of gravity and absorbs floor reaction force.

Causes of deviation:

- The foot positioned in excessive dorsiflexion or too much anterior tilt of the Socket
- Excessive stiff heel cushion or plantar flexion bumper
- Excessive anterior displacement of the socket over the foot
- Flexion contracture or posterior displacement of the suspension

b) Absent or insufficient knee flexion

Causes of deviation:

- Excessive plantarflexion foot
- Excessively soft heel cushion

- Displacement of the socket over the foot posteriorly
- Anterodistal discomfort
- Weakness of quadriceps
- Habit

2. Mid-stance phase gait deviations

a) Excessive lateral thrust of the prosthesis: The tendency of the prosthesis to rotate around the amputated limb.

Causes of deviation:

- Excessive medial placement of the prosthetic foot
- Abducted socket

b) Excessive raising of hip

- Too long prosthesis

c) Excessive dropping of hip

- Too short prosthesis
- Painful stump

d) Wide based gait

- Outset foot
- Medial leaning the pylon or shank also leads to wide based gait.

e) Narrow based gait

- Inset foot
- Lateral leaning of the pylon or shank

3. **Between mid-stance and toe off**

a) Early knee flexion (drop off):At heel off or quickly from that point, knee extension reverses & flexion starts. This knee flexion coincides with the going of the centre of gravity over the metatarsophalangeal joints. if the body weight is passed over these joints too soon ,the consequent absence of anterior support would allow early knee flexion or drop off.

Causes are:

- socket displacement excessive anterior to the foot
- Posterior displacement of the keel.
- Too much dorsiflexion of the foot or too much anterior tilt of the socket.
- Soft dorsiflexion bumper

b) Delayed knee flexion/vaulting: Body weight must be carried forward an unusually long distance before anterior support is lost. In such situations the knee joint remains in extension during the latter part of the stance phase, & the amputee might complain of “walking uphill’s” sensation. Since his centre of gravity would be carried up & over the extended knee.

Causes are:

- The socket displacement excessive posterior to the foot.
- Anterior displacement of the toe-breaker or the keel

- The foot excessively plantar flexed or excessive posterior tilt of the socket.
- Hard dorsiflexion bumper.

4. Swing phase

a) Pistoning: The prosthesis slip as foot leaves the ground in swing phase

Causes are:

- Loose or inadequate suspension
- Loose socket

b) Circumduction: Semi-circular swing of the prosthesis during swing phase

Causes are:

- Too long prosthesis
- Inadequate suspension
- Flexor muscle weakness in hip & knee
- Restricted flexion in hip & knee

3 D MOTION GAIT ANALYSIS

Motion capture gait analysis is an important innovation in the area of the medical field. It is a technique of digitally recording movements for medical applications and sports activity. It helps directly in treatment of individual patients and understanding of human gait through research. It helps to overcome two of the limitations of observational gait analysis: the lack of a permanent record and the difficulty of observing high-speed events. In addition it has the following advantages; 1. It reduces the number of walks a subject needs to do; 2.It makes it conceivable to demonstrate the subject precisely how they are walking;

In our Government Institute of Rehabilitation Medicine, Chennai, the gait lab consist of six infrared cameras, four force plates, two video cameras and wireless electromyography channels.

Data acquisition is performed by an infrared optoelectronic system and the analysis is based on the detection and three- dimensional reconstruction of passive markers positioned on anatomical markers. There are various protocols for data acquisition and marker settings .They are Davis protocol, Helen Hayes protocols and modified Helen Hayes protocol etc.

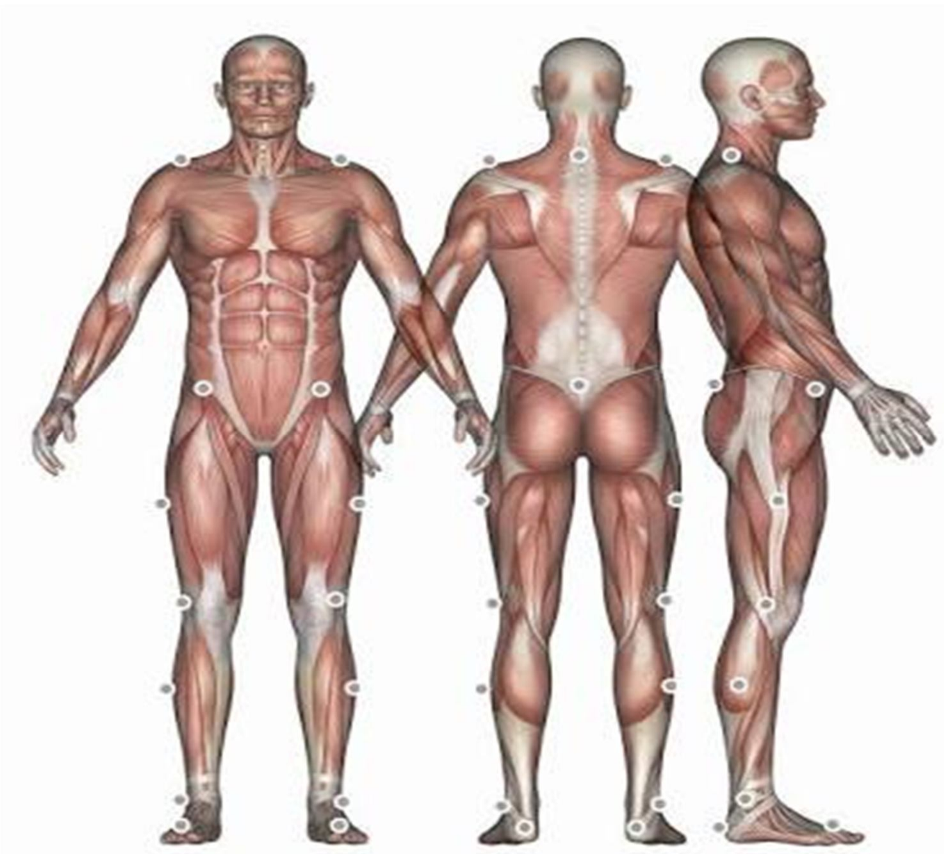

Fig 6: MODIFIED HELEN HAYES PROTOCOL

This marker motion was analysed analytically, and the software calculates the trajectory of each marker in three dimensions. This gives a complete analysis of the angular motion of each joint that is the kinematic data. In this study modified Helen Hayes protocol is used for analysing the gait changes in amputee patients. To calculate the kinetics of gait patterns, there are floor mounted load transducers, also known as force platforms, which measure the ground reaction forces and moments, including the magnitude, direction and locomotion.

Smart Analyzer is the biomechanical software used in our system able to take as input a protocol and variable number of acquired trials. It allows customized protocols to automatically create all the essential data for a complete analysis of the movement.

GAIT ANALYSIS IN AMPUTEE PATIENTS

There are many research papers based on the gait characteristics of transtibial amputee patients. Many of these research works showed that how the unilateral transtibial amputee gait varies from abled bodied persons [34, 35]. The reasons for this gait deviation are different in each journal. It is generally believed that socket fit, prosthetic alignment and prosthetic components can influence the gait. Perry et al [36] suggested that degenerative change in lumbar spine and knee will occur due to the asymmetrical walking pattern in amputee gait due to musculoskeletal alterations. Hurley et al[37], he studied about the role of sound limb in the amputee gait, outcome measures used were lower limb joint reaction force and symmetry of motion between amputees and normal population. Amputee group showed more asymmetry than non-amputee group and it was suggested that may be attributed by the variability of action of the prosthetic side.

Kinematic and temporal variables have been used to describe asymmetrical aspects of amputee gait. Murray et al [47] have shown a longer stance time on the intact limb due to difficulty or inability to spend more time in single support on the prosthetic limb, and thus a shorter swing time on the sound limb to maintain walking speed.

Robinson et al.[38] reported that prosthetic step length of transtibial amputee is slightly longer when compared to non-amputated side. In the same study it was also mentioned that stance time on the prosthetic side was less than the sound limb. Breakey et al.[34] In his study, he showed that single limb support time of the sound limb was 37 percentages of the gait cycle and 43 percentages for the sound limb.

Isakov et al.[48] found results similar to those of Breakey. The walking speed among transtibial amputees using prostheses composed of patellar tendon bearing sockets and solid ankle cushion heel feet. They found longer swing duration and stride length in the prosthetic leg, while the stance duration and single stance duration were shorter. It was because of the action of the SACH foot, since its rigid ankle speeds up the weight transfer from the heel to the forefoot, thus resulting in shorter stance duration for the prosthetic leg and the swing phase for the sound limb. Barth et al.[43] in his study he looked at the walking speed of transtibial amputee among traumatic and vascular aetiology and demonstrated that traumatic group walked at faster freely selected speed and with less energy cost than the vascular group. Despite the study were statistically significant, subjects in the study population were small.

Tibarewala and Ganguli et al.[39] reported that decreased cadence in the gait of below and above knee amputees when compared with normal subjects. Hermodsson et al[44] done study on standing balance among vascular and traumatic unilateral transtibial amputees. They found that vascular group had inferior standing balance when compared to traumatic unilateral transtibial amputees.

Breakey et al.[34] in his study showed that in early stance phase knee flexion of the amputee was less than the mean normal flexion. It was due to the prosthetic foot does not provide the controlled plantarflexion.

Kinetic analysis has also been used to reveal aspects of amputee asymmetry. Smidt et al.[40] reported that in a lower limb amputee, lower limb joint moments in all joints were are different from the mean. Winter et al .[41] done study on the important phases of power generation (+ve) and absorption (-ve) at the ankle, knee and hip joints during normal gait. A1 is the first major power absorption that occurs between 5% and 40% of the gait cycle as the result of a lengthening contraction of the ankle plantarflexors (dorsiflexion occurring) when the leg rotates over the foot under eccentric contraction of plantarflexors. A2 is the only major power generation of the ankle, which occurs between 40% and 60% of the gait cycle as the result of rapid concentric contraction of the ankle plantarflexors (plantarflexion occurring) before toe-off. From initial contact to

15% of the gait cycle, some power absorption also occurs at the knee joint (K1) due to a eccentric contraction of the knee extensors (knee flexion occurring). The only major positive burst of power at the knee (K2) occurs due to a concentric contraction of knee extensors (knee extension occurring) between approximately 15% and 25% of the gait cycle. Between 40% of the gait cycle to toe-off a power absorption burst occurs in the power profiles that represents K3, which is caused by a small extensor moment (small eccentric contraction of the quadriceps muscle), coupled with very rapid knee flexion. In the later half of swing phase, the hamstring muscles activate to absorb the energy from the swinging leg and foot (K4). At the hip joint, the first power generation burst (H1) occurs in the first half of the stance as a result of concentric contraction of the hip extensors. This is followed by a power absorption burst (H2) in the later half of the stance, the result of hip flexor activity, which absorbs energy of the decelerating thigh before it reaches the maximum hip extension. Major power generation at the hip occurs in late stance phase and early swing phase (H3) as a "pull-off burst" by the hip flexors which assist in propelling the swinging limb forward.

Hurley et al[42] compared the amputed side with the normal leg in transtibial amputees. Stance duration, vertical ground reaction force and the horizontal ground reaction forces such as anterior propulsive force and posterior force are decreased on the side with the prosthetic leg. This result in an asymmetric gait, where the unaffected leg has to compensate for the prosthetic leg.

Colborne et al.[45] showed that for unilateral transtibial amputees, in the frontal plane a large hip abductor moment, but at the knee and ankle moments were small. Frontal plane joint moments are highly variable to the high variability in the mediolateral ground reaction force.

Lemaire et al.[46] compared the gait asymmetry among unilateral transtibial amputees and able-bodied individuals. They reported a greater peak ankle plantar flexor moment at toe-off, greater knee extensor moments and greater hip flexor and extensor moments during walking for the sound limb compared to normal subjects. And also, they reported the greater ankle, knee and hip power at push-off for the sound limb of unilateral transtibial amputees compared to normal subjects. Powers et al.[49] analysed the prosthetic feet in transtibial amputees. They analysed five type of prosthetic feet Carbon Copy II, Seattle, Quantum, SACH and Flex foot. They found that speed and cadence, irrespective of the foot, were similar between the prosthetic and sound limbs. Whereas the stride length of the Flex foot was greater than the length of the SACH and Quantum, while all the others were similar (Carbon Copy II, Seattle). Regarding the joint trajectories, only the ankle showed the differences. The Flex foot had greater dorsiflexion (23.2º) than the others: Quantum 19.5º, Carbon Copy II 12.1º, Seattle 15.1º and SACH 12.0º.

RELEVANCE OF THE STUDY

Amputation is the main cause of locomotor disabilities in the world; among locomotor disability 20% of them are due to amputation. Transtibial amputation is the most common amputation among lower limb amputations. Studies on the gait parameters of amputee patient using instrumented gait analysis are being carried worldwide. But there are only very few studies on the gait characteristics of amputee patient with different aetiology. Hence, our study aimed to compare the spatiotemporal, kinematics and kinetics characteristics of unilateral transtibial amputee of different etiology (traumatic and vascular) using Instrumented Gait Analysis. This collective data will be useful for further studies on gait patterns in amputee patients.

Materials and methods

4. MATERIALS AND METHOD

4.1 STUDY DESIGN

Cross-sectional study

4.2 STUDY SETTING

The study was conducted in the Department of Physical Medicine and Rehabilitation, Government Institute of Rehabilitation Medicine, Madras Medical College, Chennai. The patients were recruited from the amputee clinic and also inpatients who were admitted for prosthetic fitting and rehabilitation. Those who satisfied the inclusion criteria were explained about the study and consent was obtained from those who were willing to participate. The prosthesis was made in the Artificial Limb Centre of Government Institute of Rehabilitation Medicine, Chennai. All the patients in our study group were using Patellar Tendon Bearing Prosthesis. The evaluation was done in 3D Motion Gait Analysis lab at our institute.

4.3 DURATION OF THE STUDY

January 2017 to July 2018 spanning over a period of 17 months

4.4 ETHICS COMMITTEE APPROVAL

Approval for the study was obtained from the Institutional Review Board, Madras Medical College, Chennai. The consent format was submitted in two different languages as expected in the population group.

4.4 STUDY POPULATION

The unilateral transtibial amputee patients walking independently without any walking aids, who visited the Amputee Clinic and also in-patients who were admitted for prosthetic fitting and rehabilitation, in Government Institute of Rehabilitation Medicine, Madras Medical College,Chennai from January 2017 to July 2018 were screened. Applying inclusion and exclusion criteria 60 patients were included in the study. Half of them were vascular etiology and another 30 patients were of traumatic etiology.

4.5 INCLUSION CRITERIA

a) Age > 40 yrs & <70 yrs

b) Unilateral transtibial amputee

c) Healthy stump

d) Using Patellar Tendon Bearing Prosthesis

e) Minimum of 2 months post amputation

f) Walking at least 10 minutes continuously at their freely selected speed

4.6 EXCLUSION CRITERIA

a) Age <40 yrs &>70 yrs

b) Bilateral amputee

c) Residual limb with deformities or ulcers

d) Using prosthesis other than Patellar Tendon Bearing Prosthesis

e) Traumatic cases associated with any other fracture or head injury

f) Traumatic cases associated with any other co morbidities

g) Any other amputation

h) Major illness

i) Mental /cognitive disturbance

j) Ambulant with walking aid

k) Uncooperative patients

4.7 SAMPLE SIZE

Approximately more than hundred transtibial amputee patients attended the amputee clinic over a period of 17 months. Those patients who satisfied the inclusion criteria underwent 3D Motion Gait Analysis in our institute. Study size was total of 60 patients, 30 traumatic amputees and 30 vascular amputees.

4.8 METHODOLOGY

Patients undergoing prosthetic fitting in GIRM were subjected for study. All patients underwent a prosthetic training at least for a time period of two to three weeks. All of them used patellar tendon bearing prosthesis. Components include patellar tendon bearing socket, supracondylar cuff suspension, exoskeletal shank piece, SACH foot. Total of 60 patients met the inclusion criteria. Thirty of them were traumatic etiology and another thirty were vascular. Consent was obtained from all the patients as per ethical committee guidelines.Before conducting the gait analysis, the residual limb was examined and the socket fit was assessed and when required the person was referred back to the prosthetist for any minor repair. Cardiology evaluation undertaken especially for vascular amputees.

This was followed by recording of anthropometric parameters. A standardised weighing machine, beam calliper and measuring tape were the instruments used. The anthropometric measurements include height, weight, ASIS width, pelvic depth, knee diameter, ankle diameter and leg length.A quantitative gait analysis was conducted in BTS 3D Gait Motion Analysis Lab in Government Institute of Rehabilitation Medicine.

Fig7 : 3D MOTION GAIT ANALYSIS LAB

Our Gait lab has 6 infrared cameras that are used to measure and quantify marker trajectories. It captures 500 -1500 frames per second. The biomechanical model used in both patients with trauma and vascular etiology groups was the modified Helen Hayes protocol.Passive markers were attached to the following locations:C7 cervical spine, acromion, sacrum ,anterior superior iliac spine, midthigh, lateral femoral condyle, mid-calf, lateral malleolus, base of the heel and dorsum of the foot on the second metatarsal head.

PATIENT ON 3D MOTION GAIT ANALYSIS LAB

As the subjects walked along the platform, the position of the marker was recorded by the motion analysis infrared cameras mounted around the periphery of the room. 4 force plates located midway along the platform and embedded flush with the floor were used to measure the ground reaction force. During gait analysis subjects were instructed to ambulate as their freely selected walking speed. A total of 8 to 10 trials of data were collected. The subjects could take rest at anytime during the experiment.

4.9 OUTCOME MEASURES

a) Temporal and Spatial parameters

i) Mean velocity (m/s): It measures the speed of the amputee person's gait.

ii) Cadence (steps/min): Measured as the number of steps taken in a minute

iii) Double support phase (percentage): Percentage of the gait cycle during two limbs in contact with the ground.

iv) Step width (cm): The distance between the centres of feet during the double limb support portion of the gait.

b) Kinematics

i) Pelvic obliquity in mid-swing (degree)

ii) Peak hip flexion in swing (degree)

iii) Peak knee flexion in swing (degree)

c) Kinetics

i) Hip power (W/Kg)

ii) Anterior/propulsive ground reaction force (%body weight)

4.10 STATISTICAL ANALYSIS

Statistical analysis was done using software SPSS 16.0 version. Students t test were used to analyse data among vascular and traumatic amputees, by comparing spatiotemporal, kinematics and kinetics data .Significant level was set to < 0.05

Results

5. RESULTS

All the unilateral transtibial amputee patients using Patellar Tendon Bearing Prosthesis who visited Government Institute of Rehabilitation Medicine, Chennai from January 2017 to July 2018 were screened.60 patients met the inclusion criteria, among them 30 were traumatic and another 30 were vascular.

DEMOGRAPHIC DATA

1. AGE & HEIGHT

The age range of patients involved in the study was 49-68 years for traumatic group and 54-69 years for vascular group. The mean age of traumatic and vascular amputees is given in the table below. Age factor variation was not statistically significant between two groups. Both groups were age matched. While comparing the height of the patients, it also showed matched data, which are not statistically significant

Table 4:Comparison of age and height among traumatic and vascular amputee patients

	Traumatic	Vascular
Mean age	56.93±5.55	62.76±4.72
Mean height	168±3.2	165±5.8

2. SEX

In this study population all the patients in traumatic and vascular amputee groups were male patients

3. SIDE OF AMPUTATION

In traumatic amputees sixteen out of thirty patients were right sided amputation and rest of them were left sided amputation.

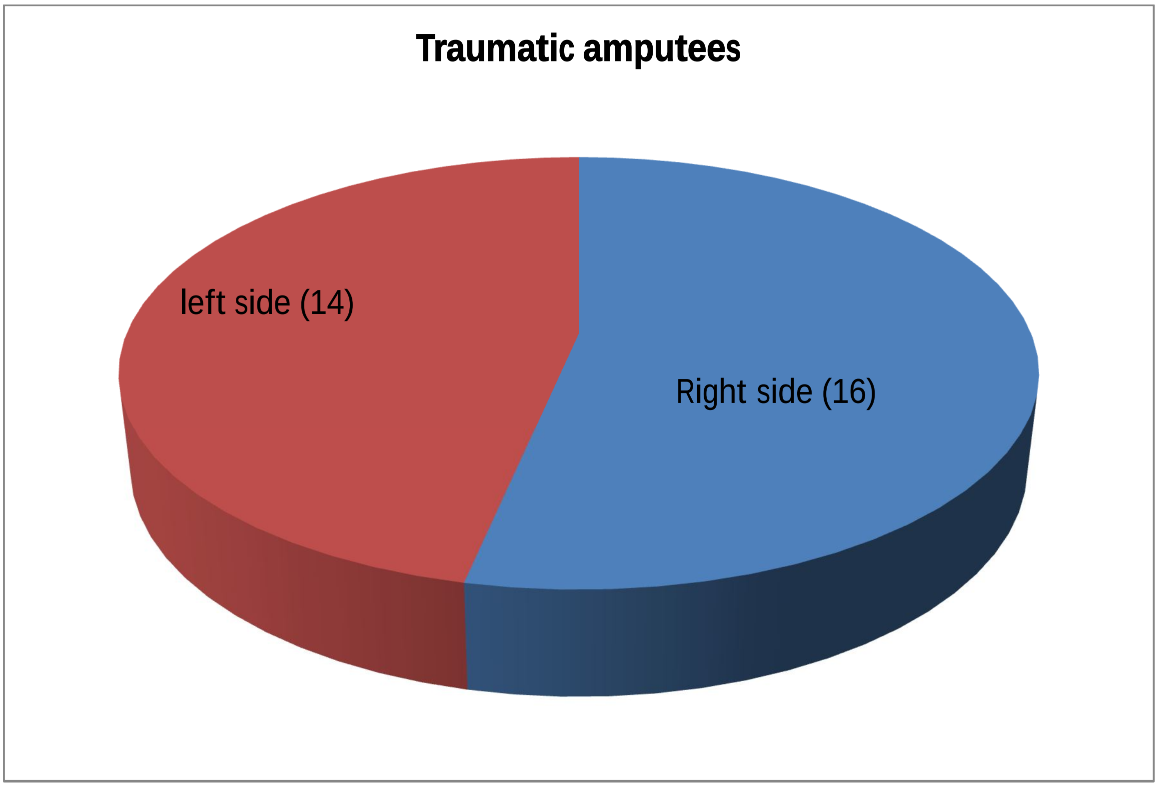

Fig 8: Traumatic amputees and amputation side

In vascular amputees right sided amputees was thirteen and that of left sided was sixteen out of thirty patients.

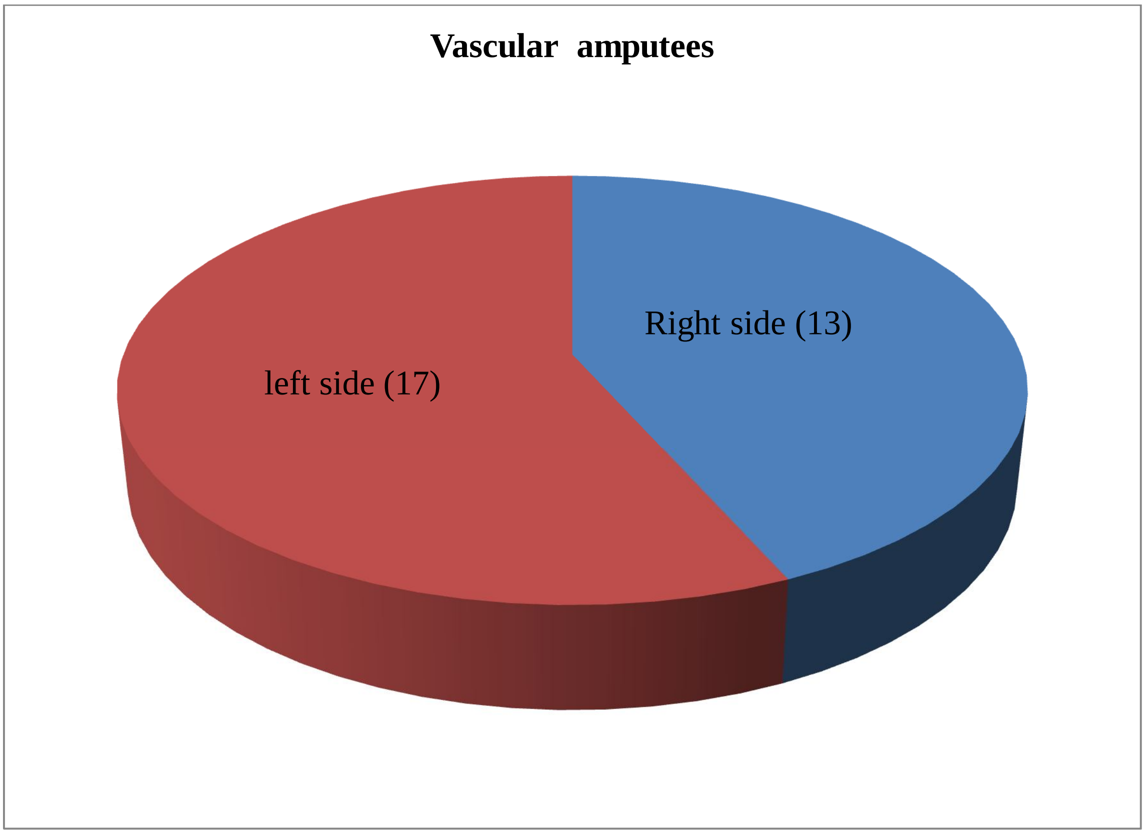

Fig 9: Vascular amputee and amputation side

4. ETIOLOGY

As in case of traumatic amputees, twenty-six out of thirty patients were due to road traffic accident, two of them were due to industrial injury one due to fall from height and one due to train accident.

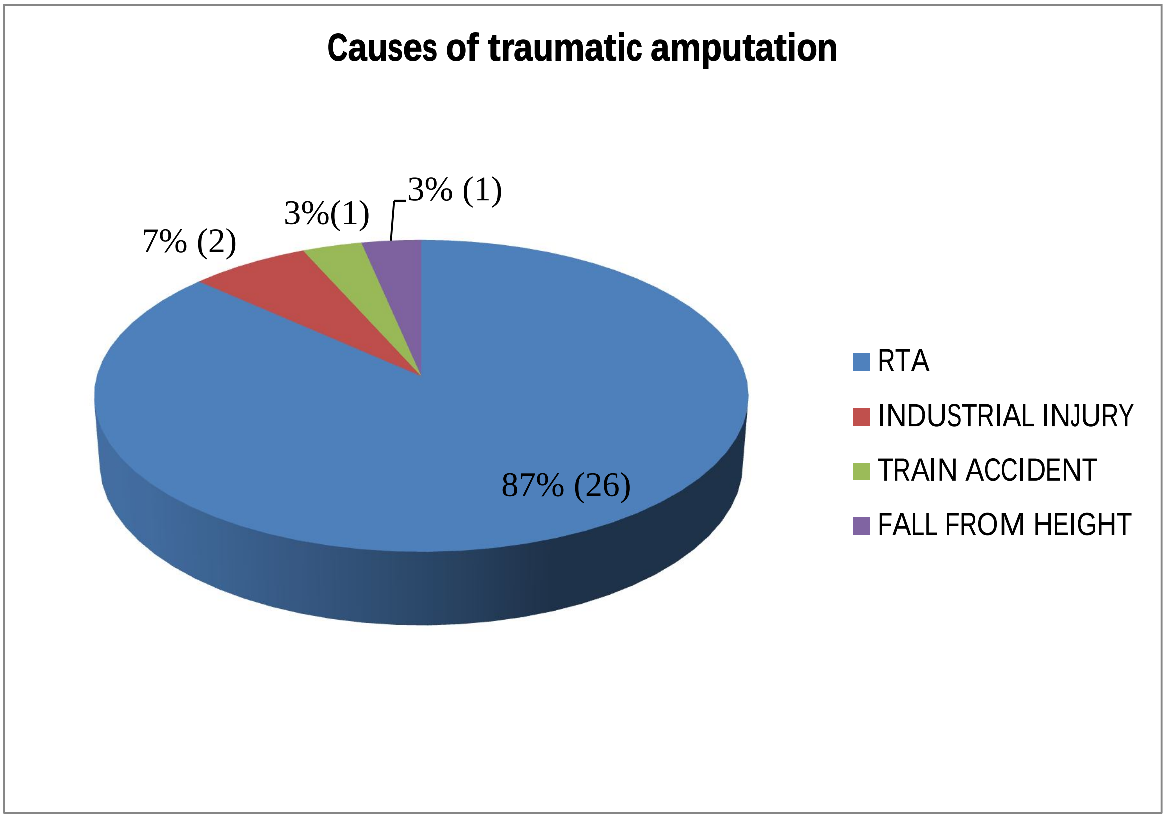

Fig 10: Different causes of amputation in traumatic group

As in case of vascular amputees all the patient's with vascular etiology was due to diabetes mellitus and its complication.

5. AMBULATION STATUS

All the sixty unilateral transtibial amputees in the study were ambulant in the community without any functional aids.

PRIMARY OUTCOME MEASURES

TEMPORAL AND SPATIAL PARAMETERS

Table 5: Comparison of temporal and spatial parameters among vascular and traumatic transtibial amputees

Gait parameters	Traumatic	Vascular	P value
Mean Velocity(m/s)	0.85±0.11	0.63±0.046	0.001*
Cadence (steps /min)	91.14±8.49	64.58±4.92	0.03*
Step Width (cm)	14.09±1.18	16.89±0.69	0.003*
Double Support Phase (%)	17.98±0.75	25.48±1.11	0.04*

*p value < 0.05 statistically significant

The above table shows the statistical analysis of temporal and spatial parameters of the traumatic and vascular transtibial amputees. Analysis of this data showed traumatic amputees had a mean velocity of 0.85±0.11, which was more than that of vascular group and it showed statistically significant.

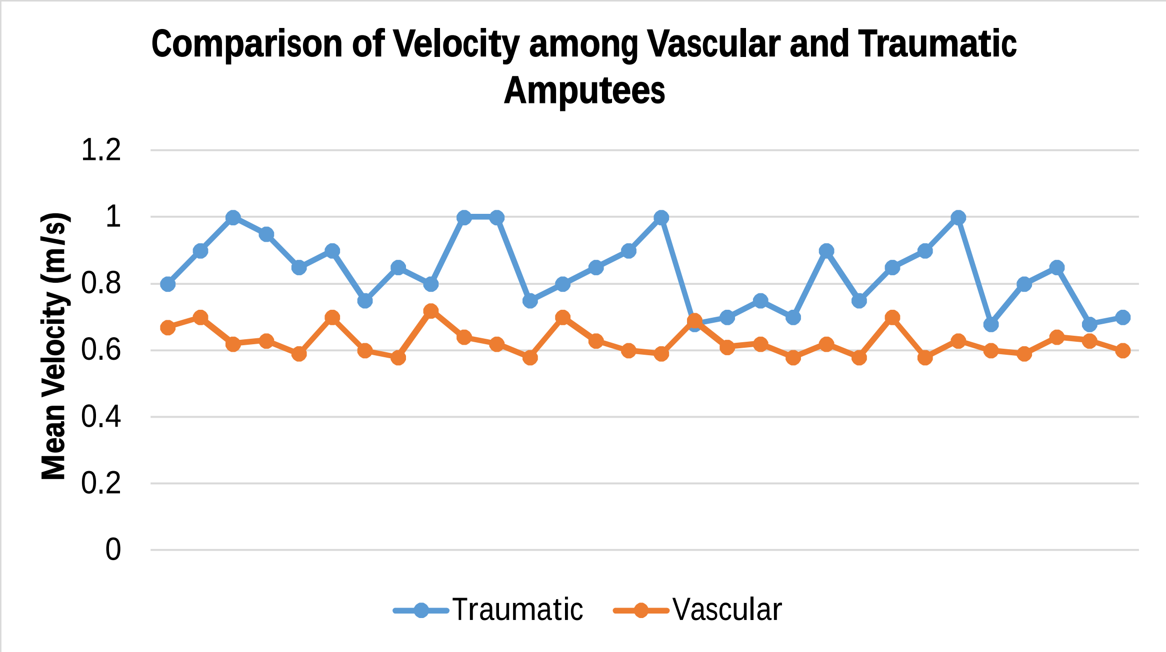

Fig 11:Comparison of velocity among Vascular and Traumatic amputees

Analysing cadence among vascular and traumatic amputees it showed that number of steps per minute is more for traumatic group while comparing with vascular amputees. It was statistically significant with p value 0.03.

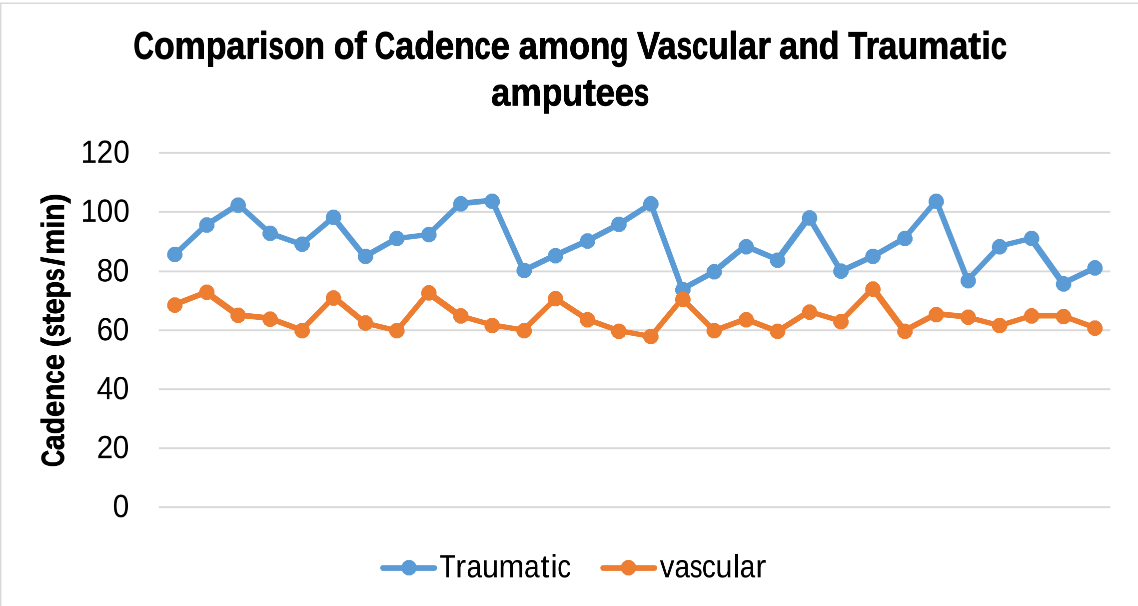

Fig 12: Comparison of Cadence among Vascular and Traumatic amputees

Other parameters such as step width and double support phase was more for vascular amputees and it was also statistically significant. These data shows vascular amputees are inferior to traumatic amputee in gait performance.

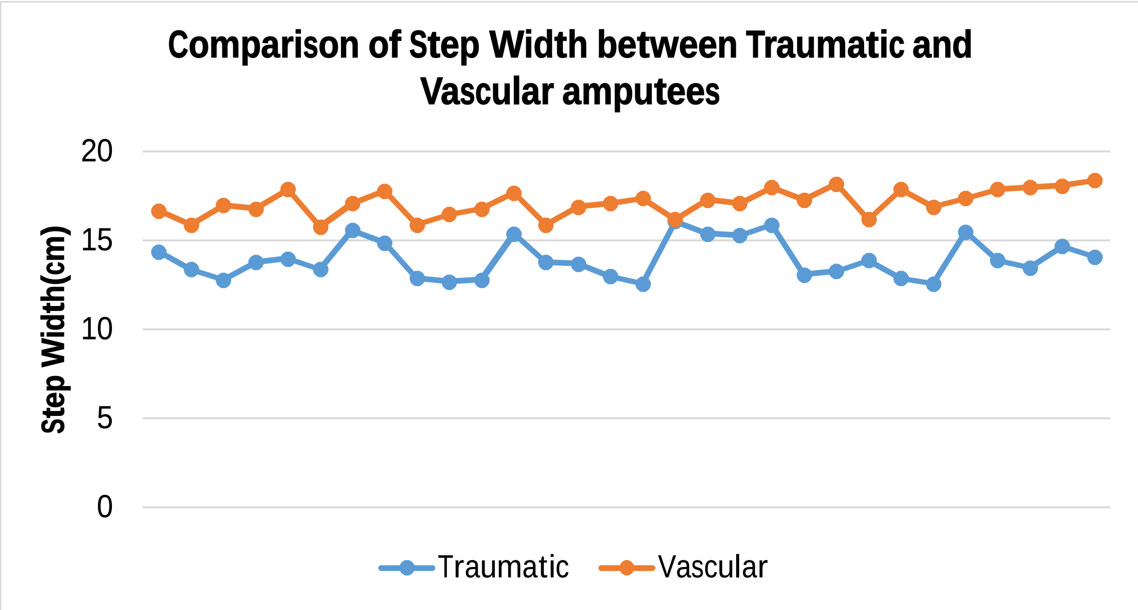

Fig 13 : Comparison of Step Width between Traumatic and Vascular amputees

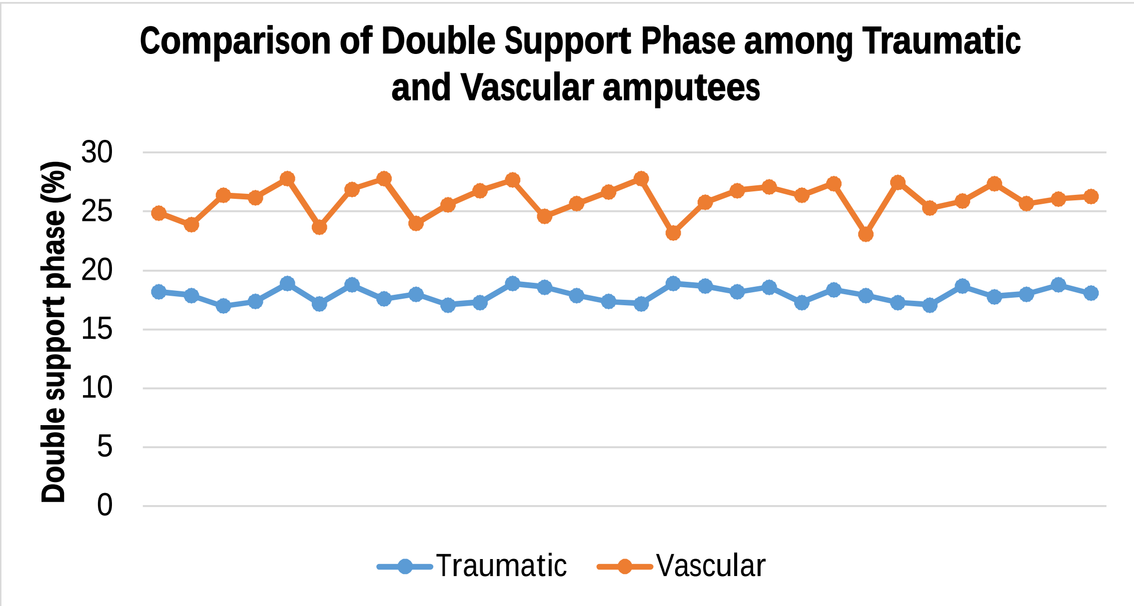

Fig 14:Comparison of Double Support Phase -Traumatic and Vascular amputees

KINEMATICS

Kinematics of the vascular and traumatic transtibial amputee given in the table no.5.

Table 6: Comparison of kinematics of the amputees

Gait parameters	Traumatic	Vascular	P value
Hip flexion	43.97±1.18	53.59±1.55	0.47
Knee flexion	63.79±0.91	68.31±1.63	0.011*
Pelvic obliquity	5.92±0.46	6.42±0.61	0.19

*p value <0.05 statically significant

Analysing the kinematics details hip flexion of vascular amputees was 53.59±1.55 degree while that of traumatic amputees was 43.97±1.18 which was less, even though it is not statistically significant. Comparing the knee flexion of vascular transtibial amputee the mean value was 68.31±1.63 degree which was more than that of traumatic transtibial amputee value 63.79±0.91 degree and these values are statistically significant also.

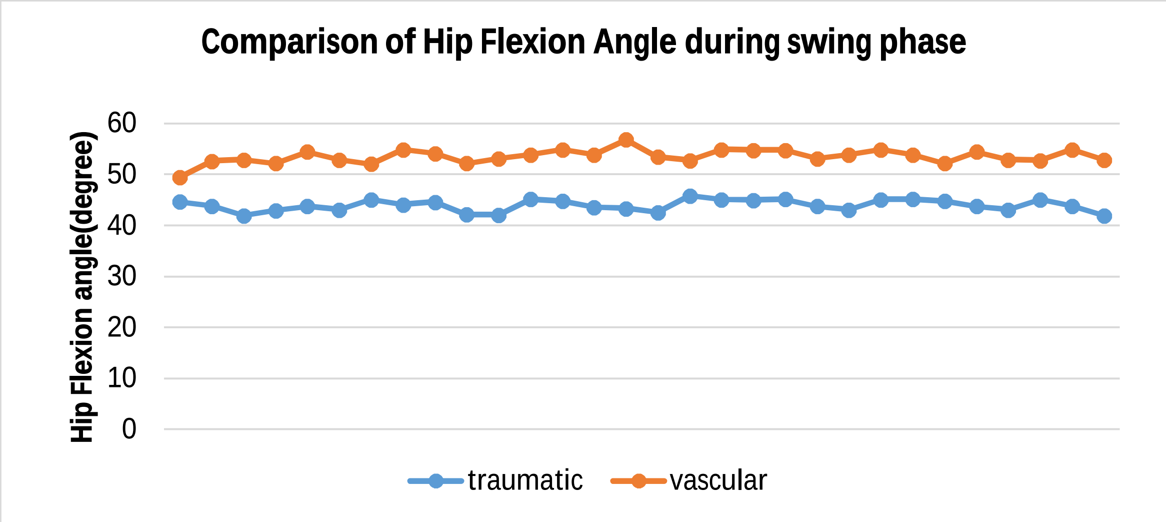

Fig 15 : Comparison of Hip Flexion Angle during swing phase

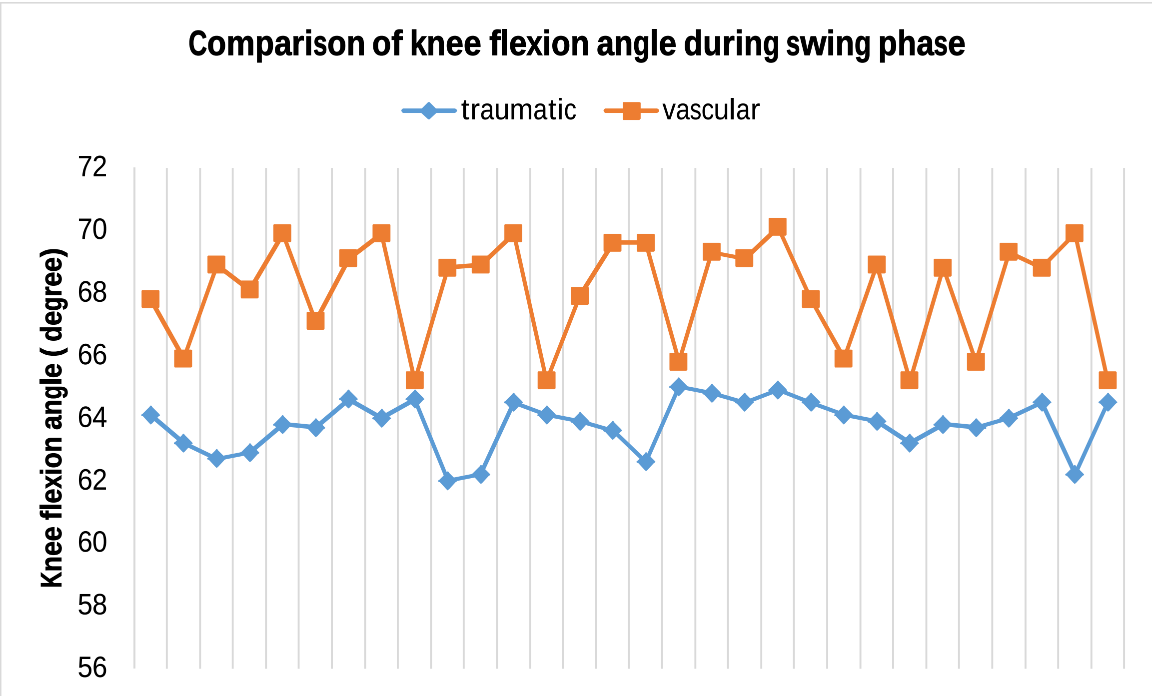

Fig 16: Comparison of knee flexion angle during swing phase

Pelvic obliquity among vascular transtibial was 6.42±0.61(mean value) which was greater in magnitude when compared to traumatic group, but these values were not statistically significant.

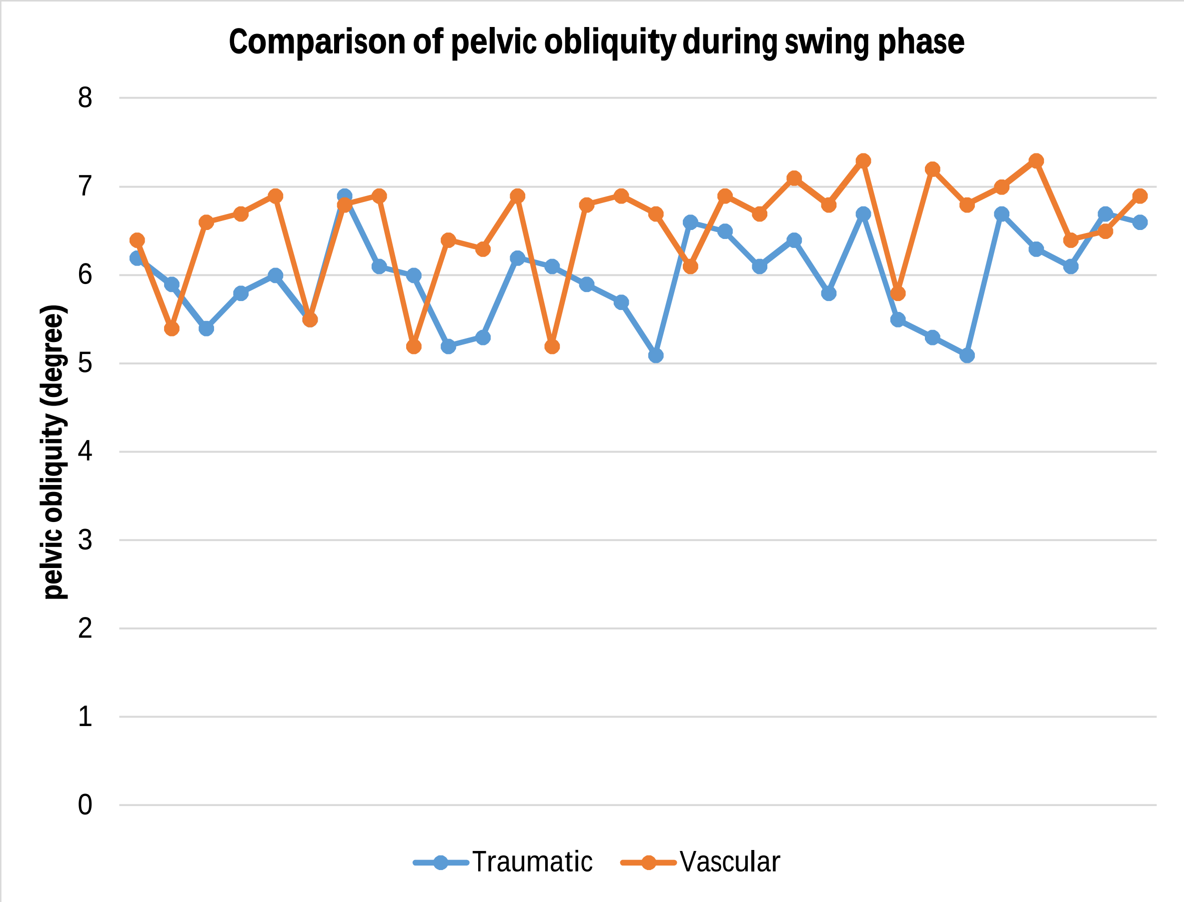

Fig 17: Comparison of pelvic obliquity during swing phase

Kinematics parameters among the vascular and traumatic amputees showed that the vascular transtibial amputees were inferior to the traumatic groups. Even though some parameters were statistically not significant.

KINETICS

Comparison of Kinetics parameters of the traumatic transtibial amputee and vascular amputee is given in the table below.

Table 7: Comparison of Kinetics of Traumatic and Vascular transtibial amputees

Gait parameters	Traumatic	vascular	P value
Hip power (W/Kg)	1.03±0.36	1.34±0.32	0.63
Horizontal ground reaction force(anterior/propulsive force)	24.15±2.60	10.25±3.46	0.09

Comparing the hip power among the traumatic and vascular amputee statistically they showed no significance between two groups. But there was difference in mean value between the vascular (mean value 1.34±0.32) and traumatic (mean value 1.03±0.36) groups .

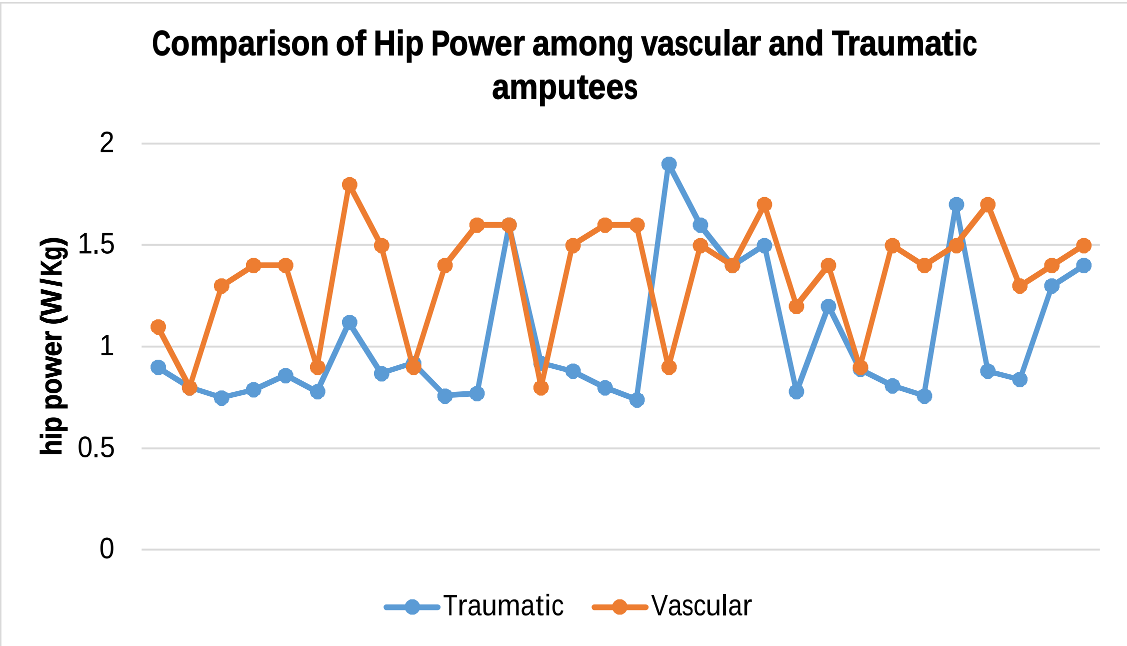

Fig no.18: Comparison of Hip Power among vascular and Traumatic amputees

Analysing the anterior /propulsive ground reaction force, it showed that the propulsive force of vascular amputee group was lesser than that of traumatic group.

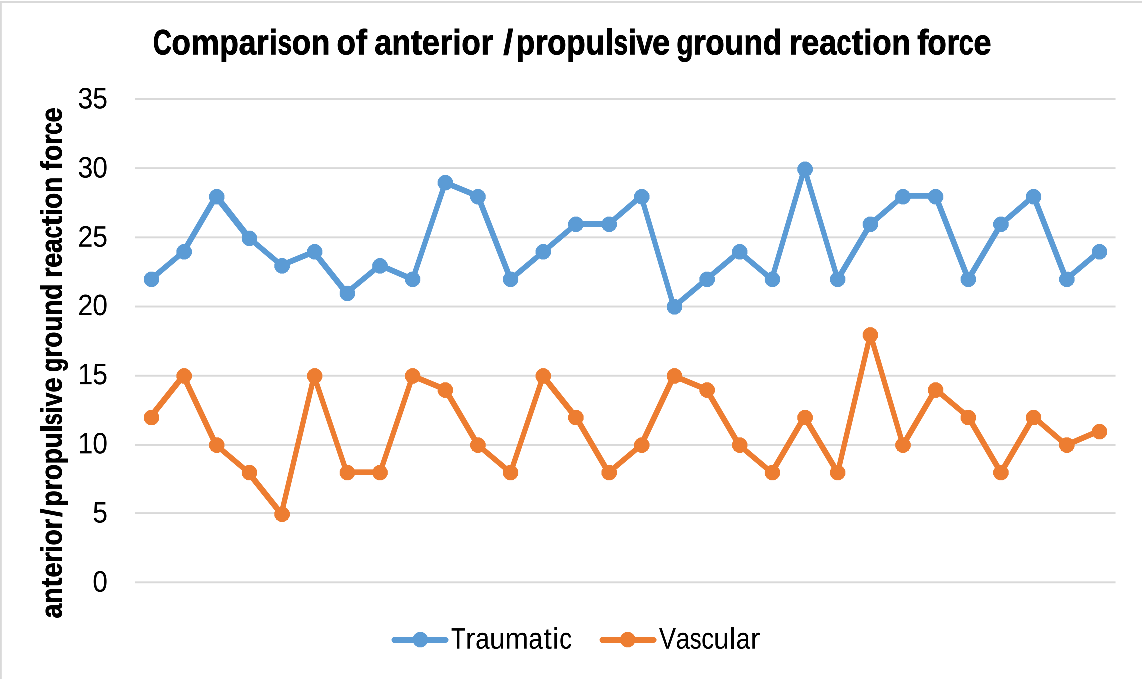

Fig no:19 Comparison of anterior /propulsive ground reaction force

Discussion

6. DISCUSSION

The aim of the study was to compare the gait characteristics among unilateral transtibial amputation due to trauma & peripheral vascular diseases . Sixty patients were included in this study, thirty traumatic amputees and another thirty vascular amputees. No interventions was done in the study.

The age difference between vascular amputees groups and traumatic amputees groups were not statistically significant. So the age related changes in the characteristics of gait was eliminated. Age wise, both sample groups are matched. All of the patients in the vascular group is diabetes mellitus and its complication. Diabetes is a growing challenge in India with estimated 8.7% diabetic population in the age group of 20 and 70 years [51].

Amputation is one major complication of diabetes. Diabetes can lead to peripheral vascular disease and also results in peripheral neuropathy. These change results in the non healing ulcers in lower extremity which results in gangrene formation and also in some cases critical limb ischemia. Critical limb ischemia is even more under recognized complication[50]. As technique for vascular reconstructions of arteries of the lower limb have become increasingly successful, primary amputations have become rare, and one would except that amputation rate would decline. However, the total number of amputations has not decreased, largely because of the greater longevity of the population.

The incidence of lower extremity amputation among patients with diabetes is almost fifty percentages higher for men than for women. The most frequently cited criteria for amputation among persons with diabetes include gangrene, infection, non healing ulcer, severe ischemic pain, local necrosis, osteomyelitis, systemic toxicity, acute embolic disease and severe venous thrombosis.

After amputation of a lower extremity, next step is rehabilitation and social reintegration. However, sometimes mobilisation is limited due to severe co morbidity. And also, additional manifestation of atherosclerosis such as coronary artery disease and stroke can often compromise the rehabilitation programmes.

Analysing the traumatic group most common cause is due to road traffic accident, other causes are train accident, fall injury and machine injury. This result was similar to the study of surget al[53].

All the amputees in this study were male patients, Surg et al[53]reported that most of the lower extremity amputation are common to men and also in vascular group. Jeffcoate et al[50] reported that amputation among persons with diabetes is more common in men it is about 50 percentage higher for men.

All the amputees in our study underwent at least a period of 3 weeks rehabilitation programmes and all of the amputees were community ambulators.

Analysing the primary outcome measures, considering the temporal and spatial parameters, the mean velocity of the traumatic amputees were more than that of the vascular group. The traumatic group also showed higher cadence and shorter double support time compared with vascular amputee group. It was similar to the study of Hermodson et al [54]. He compared the gait characteristics among traumatic, vascular and abled bodied individual. In his study he reported that mean velocity of both amputee patients were lesser than that of abled bodied individuals. While comparing the traumatic and vascular, traumatic group showed an increased mean velocity.

Po Fu Su et al[58] in his study he compared the bilateral amputees of vascular, traumatic and abled bodied individuals and concluded that at their freely selected walking speed the traumatic amputees and abled individuals, there were no significance difference of temporal and spatial parameters. But the vascular group showed much inferior to the traumatic groups. When the walking speeds were matched among the 3 groups, statistically no significance exist between these groups.

Robinson et al[38] also compared the amputee patients with healthy individual and reported that the walking speed of amputee patients was lesser than abled bodied individuals. Skinner et al[55] in his study compared temporal parameters such as walking speed, stance duration and ground reaction force and showed that higher the level amputation mean velocity decreases. Seliktar et al[56] done study on difference in gait parameters in sound limb and prosthetic limb and he concluded that sound limb has to compensate for the prosthetic limb.

Vascular group displayed a wider step width compared with traumatic amputee groups. Persons who having a inferior dynamic stability generally walk with greater lateral trunk motion and adopt an increased step with to enhance the dynamic balance. This wider base in the vascular amputee patients indicates their balance may have been compromised, because all of the vascular amputees are due to diabetes and its complication possibly attributable due to their impaired sensation and proprioception or perhaps their perception of stability. These results were similar to the study by Hermodsonst al[54], eventhough his study was statistically significant, sample size was small.

Another study by Su et al[57]vascular amputee group had significant greater fore-aft sway when compared to the traumatic group, further demonstrating the balance of vascular amputees were inferior to the traumatic group.

The vascular group showed and increased hip and knee flexion during the swing phase. Even though the hip flexion was not statistically significant the mean value of vascular amputees hip flexion degree was more than traumatic amputees. The mean hip flexion of vascular amputees was 53.59±1.55 and that of traumatic amputees was 43.97±1.18. Knee flexion angle of vascular amputees was more than vascular amputees it shows statistically significant with a P value of 0.011. These increased joint rotation of vascular amputees during the swing phase may have compensated for their poor proprioception and assist the vascular amputees in clearing the ground by lifting the foot higher above the ground.

Excessive pelvic obliquity during swing phase is a compensatory mechanism for increasing the toe clearance. This compensatory action is known as the hip hiking. This compensatory mechanism is documented in unilateral transtibial amputees as a prosthetic gait deviation. Our kinematics data showed that pelvic obliquity among both groups were statistically not significant, comparing the mean value vascular group showed some increased pelvic obliquity, as a compensatory mechanism. The rehabilitation team should carefully monitor the pelvic obliquity and train the patient to limit the excessive hiking of the hip with increased knee flexion. Better ambulator will have a decreased pelvic obliquity during walking .

It was similar to the findings of Po Fu Su et al[58]. Both vascular group and traumatic group showed a similar pelvic rotation during mid swing phase, but both groups showed a statistically not significant trends of increased pelvic obliquity compared with abled individuals. Kark et al reported that the hip flexion ,knee flexion and pelvic obliquity of unilateral transtibial amputees was more than that of abled bodied ambulatory, he didn't compare the etiological groups among amputees.

Analysing the kinetics details the vascular groups showed a trend of greater hip power near the toe off than the traumatic amputee groups, eventhough the values were not statically significant .This may be due to enhance the acceleration of the leg during pre-swing with goal of achieving greater hip flexion during mid-swing.

In normal individuals, active plantarflexion of the foot at the end of the stance phase helps to provide a push off and generate a significant power for forward progression. This anterior horizontal ground reaction force shows how active the leg, how much force exerted by the leg during the push off. In our study showed that horizontal ground reaction force of the sound limb of traumatic amputee groups were greater in magnitude than the vascular group, eventhough it is not statistically significant. This indicates that vascular amputees have the lack of strength or dysfunction in the propulsive muscles. It was similar to the study of Hermodsson et al[54].These difference in gait parameters among vascular and traumatic amputees is helpful for prosthetic dynamic alignment and it also suggest vascular and traumatic amputees to be considered as different strategies in rehabilitation programmes.

Conclusion

7. CONCLUSION

The traumatic transtibial amputees are superior to the vascular transtibial amputees in terms gait parameters such as temporal and spatial, kinematics and kinetics. Successful rehabilitation of amputee patient depends upon various factors. As a Physiatrist, we need to provide rehabilitation and prosthetic component with improved function that will enhance the amputee patients to ambulate with decreased gait deviation, at higher walking speeds and with decreased energy expenditure. These components also indeed to be specific to etiology of amputee patients .So traumatic and vascular amputee should not be considered as an entity in test situation or rehabilitation programme.

Limitations of the study

8. LIMITATIONS OF THE STUDY

The subjects in the vascular group and trauma group were not speed matched. So there shall be gait difference attributable to variation in walking speed in the study. Also, the results showed that several comparisons between the vascular and traumatic amputee groups were close to the statistically significant level , but were not statically significant .

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Annexures

ETHICAL COMMITTEE APPROVAL

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.Dhinla.S.
I Year PG in MD PMR
Institute of Rehabilitation Centre/
Madras Medical College
Chennai 600 003

Dear Dr.Dhinla.S.,

The Institutional Ethics Committee has considered your request and approved your study titled **"COMPARATIVE ANALYSIS OF KINEMATICS AND KINETICS GAIT PARAMETERS AMONG TRANSTIBIAL AMPUTEES OF TRAUMATIC AND VASCULAR ETIOLOGY USING PTB PROSTHESIS"- NO.07032017(II)**

The following members of Ethics Committee were present in the meeting hold on **07.03.2017** conducted at Madras Medical College, Chennai 3

1.Dr.C.Rajendran, MD.,	:Chairperson
2.Dr. K.Narayanasamy,MD,DM.,Dean(FAC), MMC,Ch-3	:Deputy Chairperson
3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3	: Member Secretary
4.Prof.S.Mayilvahanan,MD.,Director,Inst.of Int.Med.MMC,Ch-3	: Member
5.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3	: Lay Person
6.Thiru S.Govindasamy, BA.,BL,High Court,Chennai	: Lawyer
7.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE

CONSENT FORM

StudyDetail: “**Comparative analysis of kinematics and kinetics gait parameters among transtibial amputees of traumatic and vascular etiology using PTBprosthesis - a prospective study”**

StudyCentre : Government Institute of Rehabilitation Medicine, Chennai.

Patient’s Name :
Patient’s Age : Identification Number :

Patient / Patient’s Parents / Guardian maycheck(√)theseboxes

a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.
b) I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving reason, without my legal rights being affected.
c) I understand that sponsor of the clinical study, others working on the sponsors behalf,
the ethicalcommittee andtheregulatoryauthorities willnotneedmy permission atmyhealthrecords,bothinrespectofcurrentstudyandanyfurther Beconductin relationtoit,evenifIwithdrawfromthestudyIagreetothisaccess. However,Iunderstandthatmy identity willnotberevealedinany Tothirdpartiesorpublished,unlessasrequiredunderthelaw.I agree nottorestrictthe Useofanydata orresultsthatarisefromthisstudy.
d) Iagreetotakepartintheabovestudyandtocomplywiththeinstructionsgivenduring thestudyandfaithfully cooperatewiththestudyteamandtoimmediatelyinformthe study staff if I suffer from any deterioration in my health or wellbeing or any unexpected orunusualsymptoms.
e)Iherebyconsentto participateinthis study.

Signatureof the investigator Signature/Thumb impression of the patient

Study Investigator::Dr.DHINLA.S Patient’s name &address

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :

விபத்து மற்றும் இரத்தக்குழாய் அடைப்பினால் முழங்காலுக்கு கீழ் கால் இழந்தவர்களுக்கு செயற்கைக்கால் பயன்படுத்தி நடைபகுப்பாய்வு குறித்து ஒப்பீட்டு ஆய்வு.

பெயர் : வயது : தேதி : பங்கேற்பாளர் எண் :

.... என்பவராகிய நான் இந்த ஆய்வின் விவரங்களும் அதன் நோக்கங்களும் முறையாக மருத்துவரிடம் கேட்டு அறிந்து கொண்டேன். எனது சந்தேகங்கள் அனைத்திற்கும் தகுந்த விளக்கம் அளிக்கப்பட்டது. இந்த ஆய்வில் முழு சுதந்திரத்துடன் மற்றும் சுயநினைவுடன் பங்கு கொள்ள சம்மதிக்கிறேன்.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்து கொண்டு நான் எனது சம்மதத்தைத் தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தை பற்றி எனக்கு விளக்கப்பட்டது.

இந்த ஆய்வினை பற்றிய அனைத்து தகவல்களும் எனக்கு தெரிவிக்கப்பட்டது. இந்த ஆய்வில் எனது உரிமை மற்றும் பங்கினை பற்றி அறிந்து கொண்டேன்.

இந்த ஆய்வில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் நான் பங்கு பெறுகிறேன். இந்த ஆராய்ச்சியில் இருந்து நான் எந்நேரமும் பின் வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

இந்த ஆய்வில் கலந்து கொள்வதன் மூலம் என்னிடம் பெறப்படும் தகவலை ஆய்வாளர் இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டியினரிடமோ, அரசு நிறுவனத்திடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.

இந்த ஆய்வில் முடிவுகளை வெளியிடும்போது எனது பெயரோ, அடையாளமோ வெளியிடப்பட்டாது என அறிந்து கொண்டேன். இந்த ஆய்வின் விவரங்களைக் கொண்ட தகவல் தாளைப் பெற்று கொண்டேன்.

இந்த ஆய்வில் பங்கேற்கும் பொழுது ஏதேனும் சந்தேகம் ஏற்பட்டால், உடனே ஆய்வாளரை தொடர்பு கொள்ள வேண்டும் என அறிந்து கொண்டேன்.

இச்சுய ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன் மூலம் இதிலுள்ள அனைத்து விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்றும் தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்றும் தெரிந்து கொண்டேன்.

பங்கேற்பாளர் கையொப்பம் தேதி :

ஆய்வாளர் கையொப்பம் தேதி :

PATIENT INFORMATION SHEET

Astudytitled“**Comparative analysis of kinematics and kinetics gait parameters among transtibial amputees of traumatic and vascular etiology using PTB prosthesis - a prospective study”**is beingconducted atGovernmentInstituteofRehabilitationMedicine,K K Nagar, Chennai600083.

Thepurposeof thisstudy istoknow the effect of amputation etiology in unilateral transtibial amputee by comparing kinematics and kinetics gait parameters among vascular and traumatic groups using transtibial prosthesis with PTB socket, exoskeletal shin piece and SACH foot**.**

Theprivacyofthepatientsintheresearchwillbemaintainedthroughout thestudy. In theevent ofanypublicationorpresentation resulting fromthe research,nopersonallyidentifiableinformationwillbe shared.

Takingpartinthisstudy isvoluntary.Youarefreetodecidewhetherto participateinthisstudyortowithdrawatanytime;your decisionwillnotresultin anylossofbenefitstowhichyouare otherwise entitled.

Theresultsof thespecialstudy may beintimatedtoyouattheendofthe study periodorduringthestudy ifanythingisfoundabnormalwhichmayaidin the managementor treatment.

Signature ofinvestigator Signature ofparticipant

Place:Chennai

Date :

தகவல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :

விபத்து மற்றும் இரத்தக்குழாய் அடைப்பினால் முழங்காலுக்கு கீழ் கால் இழந்தவர்களுக்கு செயற்கைக்கால் பயன்படுத்தி நடைபகுப்பாய்வு குறித்து ஒப்பீட்டு ஆய்வு.

ஆய்வாளர் : **மரு. சி. தின்லா,**

முதலாம் ஆண்டு பட்டமேற்படிப்பு மாணவி,

மருத்துவம் மற்றும் மறுசீரமைப்பு உயர்நிலைத் துறை,

சென்னை மருத்துவக் கல்லூரி,

சென்னை-600003.

விபத்து மற்றும் இரத்தக்குழாய் அடைப்பினால் கால் இழப்பு ஏற்பட வாய்ப்பு அதிகம். இவர்களுக்கு செயற்கை கால் பயன்படுத்தி நடந்தாலும், சாதாரண மனிதர்கள் போல் நடை அளவுருக்கள் இருப்பதில்லை. இந்த ஆய்வு மூலம் நடை வித்தியாசங்கள் ஒப்பீடு செய்யப்படுகிறது.

இந்த ஆய்வையொட்டி எந்த விதமான சந்தேகங்களுக்கும் விளக்கம் பெற பங்கேற்பாளர்களுக்கு உரிமை உள்ளது.

இந்த ஆய்வில் ஆகும் அதிகப்படியான செலவிற்கு நோயாளிகளிடமிருந்து பணம் பெற்றுக்கொள்ளப்படமாட்டாது.

இந்த ஆய்வின் முடிவுகள் இறுதியில் பிரசுரிக்கப்படும். இந்த ஆய்வை பற்றிய சந்தேகங்கள் முழுமையாக தங்களுக்கு விளக்கப்படும். தொடர்பு கொள்ள வேண்டியவர் : மரு. சி. தின்லா, செல் : 7448514509

ஆய்வாளர் கையொப்பம்

தேதி :

பங்கேற்பாளர் கையொப்பம் /
இடதுகை பெருவிரல் ரேகை
தேதி :

GAIT ANALYSIS OF UNILATERAL TRANSTIBIAL AMPUTEE

NAME: AGE: SEX:

ADDRESS: PHONE.NO.

1. AMPUTATION DETAILS:

- TRAUMATIC/VASCULAR:
- SIDE AT WHICH AMPUTATION DONE:
- DURATION OF AMPUTATION:
- STUMP LENGTH:
- ASSOCIATED COMPLICATION:
- STATUS OF OPPOSITE LIMB:

2. PROSTHESIS DETAILS:

- NO.OF PROSTHESIS :
- DURATION OF PROSTHESIS USE:
- TYPE OF PROSTHESIS:
- AMBULATION STATUS:
- FUNCTIONAL AIDS:

3. MEDICAL DETAILS:

- CO-MORBIDITIES:

4. ANTHROPOMETRIC MEASUREMENTS

Weight: Height (cm):

Asis breadth (cm): Pelvic depth (cm): Right: Left:

Leg length (cm): Right: Left:

Knee diameter (cm): Right: Left:

Malleolus diameter: Right: Left:

MASTERCHART - TRAUMATIC AMPUTEES

SL.NO.	VELOCITY	CADENCE	DS PHASE%	S W	PO	H-F	K-F	HP	AP FORCE
1	0.8	85.8	18.2	14.4	6.2	42	64.1	0.9	22
2	0.9	95.8	17.9	13.4	5.9	43	63.2	0.8	24
3	1	102.6	17	12.8	5.4	43.8	62.7	0.75	28
4	0.95	93	17.4	13.8	5.8	43.1	62.9	0.79	25
5	0.85	89.3	18.9	14	6	45.1	63.8	0.86	23
6	0.9	98.4	17.2	13.4	5.5	44.1	63.7	0.78	24
7	0.75	85.2	18.8	15.6	6.9	44.6	64.6	1.12	21
8	0.85	91.3	17.6	14.9	6.1	42.2	64	0.87	23
9	0.8	92.6	18	12.9	6	42.1	64.6	0.92	22
10	1	103	17.1	12.7	5.2	45.2	62	0.76	29
11	1	104	17.3	12.8	5.3	44.8	62.2	0.77	28
12	0.75	80.4	18.9	15.4	6.2	43.6	64.5	1.6	22
13	0.8	85.5	18.6	13.8	6.1	43.4	64.1	0.92	24
14	0.85	90.4	17.9	13.7	5.9	42.6	63.9	0.88	26
15	0.9	96	17.4	13	5.7	45.9	63.6	0.8	26
16	1	103	17.2	12.6	5.1	45.1	62.6	0.74	28
17	0.68	74	18.9	16.1	6.6	45	65	1.9	20
18	0.7	80	18.7	15.4	6.5	45.2	64.8	1.6	22
19	0.75	88.5	18.2	15.3	6.1	43.8	64.5	1.4	24
20	0.7	84	18.6	15.9	6.4	43.1	64.9	1.5	22
21	0.9	98.3	17.3	13.1	5.8	45.1	64.5	0.78	30
22	0.75	80.2	18.4	13.3	6.7	45.2	64.1	1.2	22
23	0.85	85.2	17.9	13.9	5.5	44.8	63.9	0.89	26
24	0.9	91.3	17.3	12.9	5.3	43.8	63.2	0.81	28
25	1	104	17.1	12.6	5.1	43.1	63.8	0.76	28
26	0.68	77	18.7	15.5	6.7	45.1	63.7	1.7	22
27	0.8	88.5	17.8	13.9	6.3	43.9	64	0.88	26
28	0.85	91.3	18	13.5	6.1	42	64.5	0.84	28
29	0.68	76	18.8	14.7	6.7	45.3	62.2	1.3	22
30	0.7	81.3	18.1	14.1	6.6	44	64.5	1.4	24

DS PHASE - DOUBLE SUPPORT PHASE
SW - STEP WIDTH
PO - PELVIC OBLIQUITY

HF - HIP FLEXION
KF - KNEE FLEXION
HP - HIP POWER
AP FORCE - ANTERIOR PROPULSIVE FORCE

MASTERCHART - VASCULAR AMPUTEE									
SL.NO.	VELOCITY	CADENCE	DS PHASE%	S W	PO	H-F	K-F	HP	AP FORCE
1	0.67	68.8	24.9	16.7	6.4	52.9	67.8	1.1	12
2	0.7	73	23.9	15.9	5.4	52.2	65.9	0.8	15
3	0.62	65.2	26.4	17	6.6	54.5	68.9	1.3	10
4	0.63	64	26.2	16.8	6.7	52.9	68.1	1.4	8
5	0.59	60.1	27.8	17.9	6.9	52.1	69.9	1.4	5
6	0.7	71.2	23.7	15.8	5.5	54.9	67.1	0.9	15
7	0.6	62.6	26.9	17.1	6.8	54.2	69.1	1.8	8
8	0.58	60	27.8	17.8	6.9	52.2	69.9	1.5	8
9	0.72	72.8	24	15.9	5.2	53.2	65.2	0.9	15
10	0.64	65	25.6	16.5	6.4	53.9	68.8	1.4	14
11	0.62	61.9	26.8	16.8	6.3	54.9	68.9	1.6	10
12	0.58	60.1	27.7	17.7	6.9	53.9	69.9	1.6	8
13	0.7	70.9	24.6	15.9	5.2	56.9	65.2	0.8	15
14	0.63	63.8	25.7	16.9	6.8	53.5	67.9	1.5	12
15	0.6	59.9	26.7	17.1	6.9	52.8	69.6	1.6	8
16	0.59	58	27.8	17.4	6.7	54.9	69.6	1.6	10
17	0.69	70.7	23.2	16.2	6.1	54.8	65.8	0.9	15
18	0.61	60	25.8	17.3	6.9	54.8	69.3	1.5	14
19	0.62	63.8	26.8	17.1	6.7	53.2	69.1	1.4	10
20	0.58	59.8	27.1	18	7.1	53.9	70.1	1.7	8
21	0.62	66.4	26.4	17.3	6.8	54.9	67.8	1.2	12
22	0.58	63.2	27.4	18.2	7.3	53.9	65.9	1.4	8
23	0.7	74.2	23.1	16.2	5.8	52.2	68.9	0.9	18
24	0.58	59.9	27.5	17.9	7.2	54.5	65.2	1.5	10
25	0.63	65.5	25.3	16.9	6.8	52.9	68.8	1.4	14
26	0.6	64.6	25.9	17.4	7	52.8	65.8	1.5	12
27	0.59	61.7	27.4	17.9	7.3	54.9	69.3	1.7	8
28	0.64	65	25.7	18	6.4	52.9	68.8	1.3	12
29	0.63	64.9	26.1	18.1	6.5	53.2	69.9	1.4	10
30	0.61	61	26.3	18.4	6.9	53.9	65.2	1.5	10

DS PHASE - DOUBLE SUPPORT PHASE
SW - STEP WIDTH
PO - PELVIC OBLIQUITY

HF - HIP FLEXION
KF - KNEE FLEXION
HP - HIP POWER
AP FORCE - ANTERIOR PROPULSIVE FORCE